European Food Safety Authority

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SCIENTIFIC REPORT OF EFSA

Report of the Public Consultation on the EFSA Draft Opinion on "Revision of the joint AFC/BIOHAZ guidance document on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption"[1]

(Related to Question No EFSA-Q-2009-00196)

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

BACKGROUND

On 10 December 2009, EFSA's Panel on Biological Hazards (BIOHAZ) endorsed a draft scientific opinion on "Revision of the joint AFC/BIOHAZ guidance document on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption". The draft opinion had been prepared by a BIOHAZ working group composed of external experts and members of the BIOHAZ Panel.

In line with EFSA's policy on openness and transparency, and in order for EFSA to receive comments from the scientific community and stakeholders on its work, EFSA engages in public consultations on key issues. The work on guidance on carcass decontamination is such an issue, and on 22 January 2010 the draft opinion was published for public consultation until the 22 February 2010 (see Annex). EFSA has committed to publish the comments received as well as a short report on the outcome of the consultation.

Comments received

At the deadline, EFSA had received 60 submissions, from 13 interested parties (private companies, universities, governmental institutions, national public health bodies and consumer associations). All comments received were scrutinized and subsequently tabulated with reference to the author(s) and the section of the draft opinion to which the comment referred. Comments submitted formally on behalf of an organization appear with the name of the organization. The table of all comments is attached to this report– without reference to individual names – as a separate document.

1 On request EFSA, Question No EFSA-Q-2009-00196.

2 Correspondence: biohaz@efsa.europa.eu

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This compilation contains the comments received via the electronic form after the public consultation which closed on 22 February 2010. The comments received have been pasted literally in order of date of reception without any editing of the text.

Organisations that submitted comments to the consultation (in alphabetical order)

AFSSA	FRA
Canadian Mission to the EU on behalf of Health Canada	CAN
Chemische Fabrik Budenheim KG	DEU
Ecolab Deutschland GmbH	DEU
Food Standards Agency	GBR
INRA	FRA
Institute of Food Hygiene of Athens, Ministry of Rural Development and Food	GRC
Institute of Food Technologists	USA
National Medicines Institute	POL
Purac	NLD
TEST ACHATS	BEL
U.S Meat Export Federation	USA
USDA Foreign Agricultural Service	USA

Screening and evaluation of comments received

General

Editorial comments were dealt with by EFSA's secretariat. The remaining comments were discussed with the EFSA BIOHAZ working group that had drafted the original document, and presented to the BIOHAZ Panel.

Types of comments and incorporation of comments in the opinion

EFSA is grateful to the contributors for sending their comments, and these were acknowledged by the BIOHAZ Panel.

A number of comments made reference to areas within the responsibility of the Risk Manager (European Commission) and as such outside the remit of EFSA.

Many comments addressed matters on specific treatments or methodologies. The stakeholders requested clarifications on the acceptability of submitting existing data differing from what is mentioned in the guidelines and in the examples. The present guidance document refers generically to all candidate substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption, therefore it aims to provide general guidelines, and it cannot address each specific situation in detail. It is up to the applicant to use appropriate methodologies and to design the studies, which would generate the data to fit the requirements described in the guidance. The applicant should also select the appropriate materials (e.g. microorganisms), and justify the choice in relation to the specific food to be treated with the decontaminating agent. The evaluation of submissions will be performed according to a case-by-case approach.

In many comments received from non-European institutions, clarifications have been requested on the possibility of submitting data from applicants based outside the European Union, or data obtained from studies conducted outside Europe. It was emphasized that all valid scientific data will be considered, independently of the source, or of the origin of the application.

Some comments addressed the consistency of the terminology used in the guidance and this has now been harmonised. Moreover, some stakeholders asked about the possibility for submitting unpublished data. Data not public available are normally not considered by EFSA for its scientific evaluations; however, relevant data generated by industry could be submitted, and would be subjected to the scrutiny of the scientific referees.

A number of comments indicated that statistical significant pathogen reduction data does not necessarily have an impact on public health and that such an impact in general is difficult to prove. The opinion of the BIOHAZ Panel is that it is the applicant who should develop an argument based on the results obtained with respect to risks. Whether a significant pathogen reduction has impact on human health could i.e. be demonstrated through existing scientific data like published epidemiological studies or risk assessments.

The document requires an estimate of potential daily exposure of the consumer to residues from the decontaminating agents. Some stakeholders argued that the exposure may consist on a cumulative effect from many different non-food sources of such substances. EFSA does not deal with cumulative exposure, moreover the substances here are considered as processing aids, thus they should be completely removed after the decontaminating process.

Some misunderstanding arose because it was not clear if the term "resistance to antimicrobials" was referred to therapeutic antimicrobials, or also to biocides. The WG proposed to clarify the terminology in accordance with previous BIOHAZ opinions, and the wording of "acquired reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials" has been introduced where appropriate in the text.

Several comments were focused on issues concerning factors affecting the quality of the food products treated with decontaminating agents, thus addressing points out of the mandate of EFSA, which deals with food safety and not with product quality.

A number of received comments were considered not relevant by the WG, since they were based on generic assumptions, misunderstandings and personal views unsupported by scientific data.

Some comments suggested the insertion of specific citations in reference to specific treatments (i.e. superheated treatment of poultry carcasses) outside the scope of the guidance, therefore they were not taken into consideration.

Many stakeholders interpreted the studies presented as examples in the appendices as protocols to be strictly followed. The WG and Panel clarified that the appendices have to be considered only as examples; the intention is to give illustration to the applicants on how studies could be performed. Nevertheless it is up to the applicants to design the appropriate studies for the specific purpose.

The chapter of the definitions has been amended according to some of the comments received asking for harmonisation.

The draft opinion has been revised and amended only where the BIOHAZ WG and Panel agreed with the argumentation.

The Opinion was subsequently presented to the BIOHAZ Panel and adopted at the plenary meeting on 11 March 2010

APPENDIX A: COMMENTS RECEIVED (IN CHRONOLOGICAL ORDER OF RECEIPT)

ORGANISATION	CHAPTER_TEXT	COMMENT_TEXT
TEST ACHATS	General comments	En tant qu"Association de défense des consommateurs, nous sommes et demeurons totalement opposés à toute autorisation éventuelle pour ce genre de traitement.
National Medicines Institute	General comments	I have the following comments concerning revision of AFC/BIOHAZ guidance document on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption EFSA. 1) Substances used for removal of microbial surface contamination of foods of animal origin intended for human consumption, in my opinion should be considered not as liquids containing surfactants/detergents to improve cleaning process and make it more efficient, but as disinfectants - bactericidal and fungicidal products. 2) Technical Committee 216 of European Committee for Standardisation (CEN) have published since 1997, several European Standards (EN) dedicated to antimicrobial activity testing of chemical disinfectants and antiseptics 3) Regulations concerning antimicrobial activity testing of biocidals (e.g. disinfection products) should be maximally unified, regardless to organization which creates them. Actually, many differences and discrepancies are observed between CEN, EFSA, EMA, EDQM regulations, concerning disinfection and antiseptic products such as: medicinal products, medical devices, biocidal products and cosmetics, present on the market. 4) Removal of microorganisms from the surface of food should be quick and efficient. So the procedures dedicated rather to disinfectants than antibiotic drugs should be considered. Determination of antimicrobial efficacy (in log of cfu reduction value) during short time (max 1h), as proposed by several EN is more appropriate, than MIC and MBC values determination, suitable for antibiotics applied in therapy during several days. 5) Concerning point 8.3 iii. of The Guidance, MIC and MBC values deliver rather scientific information, not practical data concerning antimicrobial power – here bactericidal and fungicidal efficacy in short time – recommended by ENs should be

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		evaluated. 6) In my opinion substances described in guidance should comply with: EN 1040. 2005. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics - Test method and requirements (phase 1), and EN 1275. 2005. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics - Test method and requirements (phase 1). 7) Antimicrobial activity of products intended to surface disinfection of foods of animal origin intended for human consumption, in my opinion should comply with the appropriate standards of Phase 2 dedicated for products applied for food, industrial, domestic and institutional areas. 8) The same level of attention is required by antimicrobial activity testing and determination of biocidal efficacy of particular substance or product, then by environmental safety.
Institute of Food Hygiene of Athens, Ministry of Rural Development and Food	General comments	The text includes sufficient details about what have to be included in a dossier of application in order to be submitted to European Commission, for authorization of substances to be used for the removal of microbial surface contamination of food of animal origin. We think that the described evidences are enough. Among them a special attention should be given to the toxicological data, through presentation of extensive experiments for the substance and its derivatives. Finally we consider necessary to emphasize that the GMP and HACCP at slaughterhouses leads to the production of safe products without requiring the use of antimicrobial agents. The use of the latter, in accordance with the published data, may have unforeseen consequences for consumer health and can cause deterioration to the environment.
Canadian Mission to the EU on behalf of Health Canada		we noted that the EFSA document emphasizes a request for a demonstration of a lack of environmental effects arising from the use of antimicrobial washes. In this respect, meat processing plants in Canada must follow environmental disposal rules defined by provincial authorities, e.g. provincial Ministries of Environment. In any case, any beef carcasses exported to the EU would be free of any residues of antimicrobial chemicals provided that the antimicrobial washes were used according to Good

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		Manufacturing Practices. We also noted that the EU authorities raised the issue of possible antimicrobial resistance (AMR) that could develop subsequent to the use of antimicrobial rinses. The Veterinary Drugs Directorate of Health Canada conveyed the following comments on this specific aspect of the EFSA document: The first paragraph under section 8 of the document states that "where the formulated product has already been in use previously as "processing aid" in food products or as a food additive and it does not appear that such usage has led to the development of, or selection for antimicrobial resistance (AMR), the applicant may apply for approval based on the history of apparent safe use." The document is not however clear whether the sponsor can reference the safe use in a third country (e.g. , Canada) to support the EU registration. Furthermore, it is likely that the sponsor, and not the third country Government, has to submit data for assessment and approval by the EU. Available data on role of these substances in generating clinically important AMR are limited. The published report (cited in a paragraph in Background [lines 93-100 on page 3]: EFSA Journal 2008;[4]:659, 1-26) has already provided the latest scientific opinions on this topic. EU assessment (EFSA Journal 2008;[4]:659 1-26) concluded that there is currently no published data to conclude that the application of the four substances - chlorine dioxide, acidified sodium chlorite, trisodium phosphate and peroxyacids to remove microbial contamination of poultry carcasses will lead to the occurrence of acquired reduced susceptibility to these substances or to antimicrobial resistance. Therefore, unless new evidence indicates otherwise, there is no reason to anticipate any AMR due to beef products treated with antimicrobial rinses. Indeed the FAO/WHO Expert Committee evoked above also stated that "there is no evidence to indicate that the use of chlorine containing disinfectants and its alternatives are associated with acquired antimicrobial resistance to therapeutic agents".
USDA/FAS	General comments	Can you please clarify whether you will be addressing the domestic use of pathogen reduction treatments (PRTs) differently from non-EU use of the same PRT? Will there be separate criteria guidance issued to specify the residue standards and microbial standards to be applied to imported product that may undergo pathogen reduction treatments?

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USDA/FAS	9. INFORMATION NECESSARY FOR THE EVALUATION OF THE TOXICOLOGICALENVIRONMENTAL IMPACT OF THE SUBSTANCES	The environmental aspects of treatments in exporting countries are beyond the scope of measures that can be applied to imported product, so this guidance would appear to only apply to treatments when used within the European Union. Please confirm. How would these requirements apply to imported products?
USDA/FAS	Background	Resistance to therapeutic antimicrobials is primarily gained through exposure to therapeutic antimicrobial compounds themselves when used for human and animal treatment, not to sanitizer and disinfectant treatments. It would be impossible to attribute any anti-microbial resistance to the specific use of particular pathogen reduction (disinfectant) treatment. How would these requirements apply to imported product?
USDA/FAS	8. INFORMATION NECESSARY FOR THE EVALUATION OF THE POTENTIAL EMERGENCE OF ANTIMICROBIAL RESISTANCE (AMR)	Most existing and newly proposed pathogen reduction treatments will utilize ingredients that have uses in addition to pathogen reduction treatments (PRTs) for meat surfaces (in addition to uses for food processing aids or food additives noted in the guidance [lines 437-439]). Examples include water disinfection, sewage disinfection, hard surface disinfectants, topical skin disinfectants, laundry, swimming pools, and cosmetics. The total amounts of the ingredients used in PRTs that are used for purposes other than meat processing are usually much greater for alternate treatments than used in meat processing. The potential of the development of resistance to therapeutic antimicrobials by the use of PRT ingredients on meats will need to be evaluated in the context of the broader uses of the ingredients. What information should be submitted and how will the evaluation of ingredients take into account the broader use of PRT ingredients and the non-specific of action of most PRT ingredients as it relates to the possible development of resistance to therapeutic antimicrobial drugs?
USDA/FAS	1. INTRODUCTION	The introduction section states that one of the other relevant considerations mentioned in an old report, the Scientific Committee On Veterinary Measures Relating To Public Health (SCVPH) report from 1998, is the impact of the treatment on product quality. However, the current document does not elaborate on the meat/poultry quality data. Can you please explain how this will be addressed? It is our experience with generally recognized as safe (GRAS) determinations for antimicrobial treatments that the meat/poultry quality and treatment efficacy data are linked together. A data package in a submission for approval in the United States should include both efficacy data and quality data. For antimicrobial agents used during the processing of meat and poultry, it is usually requested (as evidence) that the quality of the meat and poultry is not degraded by the treatment. To determine this, the U.S. submitter should provide thiobarbituric acid (TBA) values and fatty acid profiles for treated and untreated

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		(control) product in conjunction with the efficacy data.
USDA/FAS	APPENDICES	Please clarify the purpose of the example experimental designs in the three appendices. Will an applicant need to perform exactly the protocols provided in the appendices? If an applicant conducts such an efficacy test, will that one test be sufficient?
USDA/FAS	3.2 Summary document	Section 3.2 calls for existing authorization in the European Union (EU) and other countries. If the applicant is applying for authorization, what existing authorization within the EU is expected? Would this be authorization within the EU for other uses? We recommend that you also request analysis and approvals for the ingredients and treatment from international standard setting bodies, especially the Codex Alimentarius, Joint FAO/WHO Expert Committee for Food Additives, Joint FAO/WHO Joint Expert Meetings on Microbial Risk Assessment, and relevant results from ad-hoc FAO/WHO Expert Committees.
USDA/FAS	5. CONSUMER EXPOSURE ASSESSMENT	Section 5 indicates that an estimate of potential daily exposure of the consumer to residues, degradation products and any relevant reaction by-products present in the treated food must be provided. However, the document does not specify if cumulative exposure calculations must be provided. Are these calculations required? For instance, if the proposed antimicrobial is already used in food production, U.S. submitters must estimate exposure using consumption data for all the approved uses of the proposed antimicrobial to determine the cumulative estimated daily intake and cumulative estimated exposure. It should also be recognized that exposure may arise from non-food applications of the PRT ingredients (e.g. through water, air, or cosmetic products).
USDA/FAS	6. TOXICOLOGICAL AND ECOTOXICOLOGICAL DATA	Section 6 indicates that previous toxicological assessments of the EU may be applied. Will references and analyses by international committees or other nations be considered where relevant?
USDA/FAS	7. INFORMATION REQUIRED TO ASSESS THE EFFICACY OF A FORMULATED PRODUCT	In section 7, please clarify what information is required for the assessment of the efficacy of products. The appendix examples suggest an efficacy requirement for statistical tests of at least a 50% reduction in prevalence and for a 0.5 log 10 cfu/gram reduction in mean concentration. Does this mean that a treatment that gives only a 30% reduction in prevalence or a 0.3 log 10 reduction would not be permitted? A 50% reduction in prevalence may require multiple treatments, each of which individually might not meet a 50% requirement. Would an overall treatment that only achieved a 30% reduction in prevalence be rejected even though this would have a significant health benefit? Further, the draft guidance is silent on the issue of replicate efficacy trials. Microbial reduction efficacy studies commonly involve replicate trials to assure a sample

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		representative of variable operating conditions (e.g., flocks, days, processing lines, slaughter plants) and/or due to practical limitations on laboratory capacity to process a large number of samples at a given time. For example, when is it appropriate to pool data from replicate trials to estimate the treatment effect? How will EFSA interpret the results if there is heterogeneity of treatment effects across replicates?
USDA/FAS	General comments	For an in-use product, presumably in another nation, the data requested does not appear to include data from in-use commercial settings from routine production. Such data is unlikely to have parallel controls (except by comparison to another similar plant not using the treatment). However, such data is extremely useful in verifying if the actual performance of a treatment in a commercial setting is the performance expected from laboratory and pilot-scale controlled tests. Will the EFSA require or consider this type of information?
USDA/FAS	7. INFORMATION REQUIRED TO ASSESS THE EFFICACY OF A FORMULATED PRODUCT	Section 7, part vii, specifies that tests should be made with pathogenic bacteria, taking into account strain diversity. Since there may be hundreds of different strains of potential pathogens, please clarify what is needed to satisfy this requirement? Section 7, part ix, appears to conflict with section 8.1 (lines 479 to 483). Section seven seems to imply that it will be a requirement that any treatment ingredient be neutralized before discharge, but section 8.1 states that no tests about development of antimicrobial resistance (AMR) of environmental bacteria are required if the product is neutralized before discharge. Some clarification as to the requirement for neutralization would be useful. Will neutralization be a requirement on all processing facilities? Section 7, part ix, also refers to the removal of product by filtration. Filtration is clearly ineffective for removal of dissolved substances, the form of all treatments of which we are aware. Is there some expectation that powders or other solids be used as treatments? Section 7, part xii, has requirements for an applicant to provide data on existing facilities. This would require an applicant from the EU to obtain data from processing facilities in other countries and obtain the cooperation of non-EU private facilities. What mechanism will be put in place in order to facilitate cooperation? Section 7, part viii, calls for "information on natural or acquired reduced susceptibility to the formulated product." The information on natural susceptibility appears to be redundant here as this would be established by the extensive efficacy tests described elsewhere in the document. Data on acquired susceptibility, also requested in Section

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		7, part xii, calls for an entire new class of experimental and performance data. Clarification is requested as to the requirements for data concerning reduced susceptibility.
USDA/FAS	8.1 Pre-market evaluation	The requirements for a pre-market evaluation in section 8.1 appear impossible to meet for any novel treatment that may be proposed. Lines 481-488 specify that an upstream-downstream sampling be performed and that bacteria isolated from sediment and wastewater plants be examined. Clearly for a novel treatment, not yet in use, such data will not exist. Further, even for in-use treatments, the requirement would also require cooperation of private facilities in other nations. Finally, it is highly improbable that any useful information about the effects of potential discharges on AMR of bacteria in sewage plants could be discerned. Sewage plants will, of course, have inputs from many sources, have a myriad of trace-levels of household disinfectants, have bacteria coming directly from humans and animals, and have, in most facilities, bacteria and chemicals from surface water runoff. What is the rationale and scientific basis for these requirements?
USDA/FAS	8.1 Pre-market evaluation	Section 8.1 of the guidance for pre-market evaluation is similar to the U.S. government's guidance procedures for notification and protocol submission of new technologies. However, where EFSA specifies that pre-market evaluation will include laboratory experiments, our guidance includes: 1) validated analyses; 2) peer-reviewed journal articles; and 3) prototype production results. Will the EU consider submissions which include all U.S. inclusions but not specifically prescribed laboratory experiments? If not, what is the rational and scientific basis for this requirement?
USDA/FAS	9. INFORMATION NECESSARY FOR THE EVALUATION OF THE TOXICOLOGICALENVIRONMENTAL IMPACT OF THE SUBSTANCES	Section 9 calls for generic assessments of environmental impacts. Upon acceptance of a dossier with its generic environmental assessment and approval of a treatment, will individual plants then be exempt from having further regulatory requirements applied to their discharge? Section 9 does not appear to include a request for environmental information from processing plants that may be in operation and using a proposed treatment elsewhere. The practical experiences of existing facilities would provide valuable information in addition to the generic calculations outlined in Section 9.
USDA/FAS	6. TOXICOLOGICAL AND ECOTOXICOLOGICAL DATA	The environmental assessment requires all available ecotoxicity data to be submitted. As many pathogen treatments have been in wide use for other purposes such as water disinfection (e.g. chlorine and hypochlorus solutions, chlorine dioxide, and chloramines) "all available information" could comprise hundreds to thousands of reports and papers. The request for "all available information"may be appropriate for a novel compound, but unrealistic for many of the in-use treatments in use. In lieu of

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		that requirement, we suggest requiring appropriate reviews of the literature where there may be extensive literature on the ingredients used in the treatment. There is no cut-off or threshold values specifying the need for an environmental assessment for the materials as may be discharged from the plant either with or without neutralization. We recommend defining levels of residue discharge that are not of environmental concern, such as the application of drinking water standards. Would the EFSA consider this approach as satisfactory?
USDA/FAS	1. INTRODUCTION	We suggest that the example experiments be revised to include pre-treatment measurements. The example experiments in the draft for evaluating efficacy specify only treatment with water only versus treatment with water and an additive. At a minimum, however, treatments (with or without an additive) should be compared to "a non-treated control group" (lines 191-192). For example, treatment (with or without an additive) may increase prevalence relative to an untreated control group due to cross-contamination. The inclusion of a non-treated (or pre-treatment) control group is standard practice in microbial reduction efficacy studies reported in the scientific literature.
INRA	Background	line 59 we suggest to add the following sentence : "It was demonstrated that the treatment of poultry carcasses with superheated steam is an efficient method for microbial decontamination (Kondjoyan et al, 2008)"
INRA	REFERENCES	line 706 we suggest to add the following reference : Kondjoyan A, Portanguen S, 2008. Effect of superheated steam on the inactivation of Listeria innocua surface-innoculated onto chicken skin. J Food Engineering 87, 162-171
Ecolab Deutschland GmbH	Background	Line 78-82 Regarding EFSA, 2005 b) Company Ecolab has additional data available to show the effective killing or reduction of pathogenic bacteria on poultry carcasses. In 2005 the BIOHAZ panel has not requested additional data, even not after request of Ecolab.

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		Line 90-92 The resistance could be developed following the improper use or storage of the substances resulting in a decease in their concentration (e.g. by degradation of the active substance or interference with organic soil) and, hence, in effectiveness. Line 93-97 The long history of use of the four substances (incl. acidified sodium chlorite and peroxyacids) has result in a lot of data out of the practical use. The data are not official published but available in the companies selling this products.
Ecolab Deutschland GmbH	7. INFORMATION REQUIRED TO ASSESS THE EFFICACY OF A FORMULATED PRODUCT	Line 380-384 Or re-growth of the respective pathogen under storage conditions? Line 402-408 / 415-416 / 420 Formally this should be part of chapter 8.
Ecolab Deutschland GmbH	8. INFORMATION NECESSARY FOR THE EVALUATION OF THE POTENTIAL EMERGENCE OF ANTIMICROBIAL RESISTANCE (AMR)	Line 437-439 How would this be demonstrated? How many studies according to which principle and design would be sufficient? Line 452 Who will then decide what to do? Applicant? Authorities? Line 453-454 Standardized methodology for such testing is not available (SCENIHR activities ongoing, to give guidance) Line 457-458 This is not necessarily true. There may well be a significant level of resistance before application of such a product, due to medication during animal husbandry. Line 465 Resistance to antimicrobials including the biocide itself or only - as mentioned below

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		- therapeutic antimicrobials? Line 467 A lower concentration reflects a misuse of the product and should not be taken into account for evaluation. ne 508-509 There are no standardized methods for biocide resistance are available Line 513 MIC, appropriate for therapeutic antimicrobials, not for biocidal substances. MBC appropriate for biocidal substances Line 519-520 These publications are (probably) valid for antibiotics only.
Purac	6. TOXICOLOGICAL AND ECOTOXICOLOGICAL DATA	Previous toxicological assessments of the EU may be referred to. Will references and analyses by international committees or other nations be considered where relevant?
Purac	7. INFORMATION REQUIRED TO ASSESS THE EFFICACY OF A FORMULATED PRODUCT	Tests should be made with pathogenic bacteria, taking into account strain diversity. Please clarify, sence there may be hundreds of different strains of potential pathogens.
Purac	7. INFORMATION REQUIRED TO ASSESS THE EFFICACY OF A FORMULATED PRODUCT	Will neutralization be a requirement on all processing facilities?
Purac	7. INFORMATION REQUIRED TO ASSESS THE EFFICACY OF A FORMULATED PRODUCT	Filtration is not the right tool for removal of dissolved substances,. Please clarify.
Purac	General comments	Existing food additives have a special status. Does the fact that a substance is approved under 98/8/EC [Biocides Directive] justify a special status [limited dossier]?

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Purac	8. INFORMATION NECESSARY FOR THE EVALUATION OF THE POTENTIAL EMERGENCE OF ANTIMICROBIAL RESISTANCE (AMR)	In chapter 8. first sentence we propose to replace "formulated product" by "active ingredient in the formulated product". Food additive monographs deal with the additive at a much higher concentration than the concentration used in a formulated product.
Institute of Food Technologists	1. INTRODUCTION	Founded in 1939, the Institute of Food Technologists is a not-for-profit scientific society with more than 18,000 individual members working in food science, technology, and related professions around the world. We appreciate the opportunity to comment on the draft guidance document. Line 193 reads "the best way to validate efficacy is to perform large scale in-plant studies". Upon first read, this could be interpreted as encouragement to intentionally introduce pathogens into a facility. While this is clarified in the appendix, using flocks that have tested positive for Campylobacter, IFT encourages clarification here. The Institute of Food Technologists also suggests that pilot studies outside a production atmosphere be considered as acceptable to in-plant studies
Institute of Food Technologists	7. INFORMATION REQUIRED TO ASSESS THE EFFICACY OF A FORMULATED PRODUCT	Founded in 1939, the Institute of Food Technologists is a not-for-profit scientific society with more than 18,000 individual members working in food science, technology, and related professions around the world. We appreciate the opportunity to comment on the draft guidance document. Line 417 notes post market monitoring for efficacy but does not give a timeframe. Additional guidance on post market monitoring would be helpful.
Institute of Food Technologists	8.1 Pre-market evaluation	Founded in 1939, the Institute of Food Technologists is a not-for-profit scientific society with more than 18,000 individual members working in food science, technology, and related professions around the world. We appreciate the opportunity to comment on the draft guidance document. Lines 474-477 lists the organisms that should be considered. Shiga toxin producing E. colis might also be appropriate for consideration. Lines 474-477 also state that tests should be performed for the "development of resistance to therapeutic antimicrobials". It was not clear if the antimicrobial producer should assess the potential for resistance in these organisms even if their product is

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		not "therapeutic", or if this meant organisms demonstrating resistance to the antimicrobial of interest should also be tested for cross resistance to "therapeutic" antimicrobials? Additional clarification is needed.
Food Standards Agency	General comments	In several places in the text (e.g. pages 3 and 6) one of the criteria listed for considering a decontamination process to be efficacious is that the reduction in pathogen levels it brings about has a positive impact on the reduction of human illness cases. This is obviously a key required outcome but I am wondering how you envisage the applicants demonstrating this? If a substance is not approved for use then any product treated with it, even from large-scale trials, would not be allowed into the food chain, so it would not be possible to directly assess reduction in human illness cases associated with its use. It would be useful to clarify what information you would expect applicants to supply or suggest some approaches they could take e.g. modelling approaches.
Chemische Fabrik Budenheim KG	General comments	Dear Sirs, I really appreciated the draft of revision guidance document. I Was wondering why hydrogen peroxide as the simplest "decontamination agent" from the peroxy-functions has not been mentioned in the guidance, whereas the peroxy-acids have been. May I conclude that hydrogen peroxide is covered by the assessment of the peroxyacids?
Institute of Food Technologists	8.1 Pre-market evaluation	Lines 481-485- regarding influence on the environment: it's recommended that environmental bacteria from around wastewater plants be isolated. It is not clear if data from around 1 plant is sufficient. IFT can envision substantial variation in microflora between wastewater treatment plants around Europe.
Institute of Food Technologists	8.2 Post-market evaluation	Line 501- says seasonal changes should be taken into account. It is not clear how many facilities should be tested in geographically different areas.
Institute of Food Technologists	APPENDICES	Appendix A: the size of the meat pieces seems small. Larger pieces are warranted.
Institute of Food Technologists	General comments	IFT commends EFSA for considering the environmental impact of discharged antimicrobials. From an overall viewpoint, there seems to be considerably more emphasis put on the environmental aspect as opposed to food safety (e.g., the public health benefits that might be gained by the introduction of new antimicrobials). These requirements will probably discourage the introduction of new compounds.

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AFSSA	General comments	AFSSA underlines the net improvement of this guidance document compared with the first version due to the inclusion of examples of study designs and precisions on the type of data that a dossier should include for the evaluation of the potential emergence of antimicrobial resistance; However, the document contains certain number of terminological and methodological inaccuracies that are detailed below: Many recommendations in this document are not clearly delineated: oEx 1: it is written on Line 387 that non-pathogenic microorganisms should be counted. The reader has no information on the basis for the choice of these microorganisms or on the number of genus/species/strains. oEx 2: when comparing numbers of bacteria, what level of statistical significance is to be used to consider there is a difference, and is just a significant difference enough to conclude there is an effect? Inexplicit requirements could lead to information being judged differently by different experts, agencies or Member States, and to some degree of arbitrariness. - While it was repeatedly written that the text applied to different animal species at different stages of production, the text is biased towards poultry. It seems that guidelines defined for application to carcasses in a slaughterhouse cannot be fully compatible with guidelines that should be put into practice for finished products. - On the subject of efficacy, the whole document focuses on efficacy as such, including immediate efficacy, maintaining efficacy over time and the risk of microorganisms persisting due to lower susceptibility, but: o What about evaluating the effects on spoilage flora with possible risks to human health? oWhat about the impact of sub-lethal concentrations on the expression of virulence genes? While this is a relatively new subject of exploration,it is important to integrate this point in the requirements straight away, asking for at least a bibliographic review. - The terms "microbial" (in the title), "microorganisms", "pathogenic bacteria" and

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		"pathogenic microorganisms" are employed indifferently throughout the document., These generic terms may cover contaminants other than bacteria such as viruses or mould. To take the example of viruses, such as noroviruses, are these to be considered to lie within the scope of this guidance document? This point should be specified in a foreword. - Throughout this document, a variety of terms are used. These include "substance" (in the singular and plural), "product", "formulated product", "decontaminating agents and "decontamination agent". Furthermore, the term "substances" appears in the title while in the "Definitions" chapter (pp. 27-28), only the term "formulated product" is defined ("The ready-to-use product for which authorisation is sought"). This definition assumes that the products are not diluted before use, yet line 317—which describes the application method—specifies "the intended doses to be used", and lines 407-410 "justification of the concentration of the product formulation proposed should be experimentally demonstrated". This needs to be clarified as specified in chapter 7. In addition to this need for clarification, harmonisation and consistency, there is the problem of the integral composition of a product that could contain a single substance or, several substances declared as active plus one or more co-formulants. The latter can play a role not only with respect to the product's intrinsic activity but can also contribute to lowering susceptibility (e.g.: acid or alkaline pH, surface active agents). -The word "antimicrobial" has been used in the past to designate a decontamination agent (EFSA, 2005, 2008). To avoid confusion, we suggest, as seen in some places in the document (including the definition section), systematical use of the adjective "therapeutic" before "antimicrobials".-
AFSSA	1. INTRODUCTION	Whatever chemical decontamination process is used, one is faced with the tailing off phenomenon that characterizes the decontamination kinetics: a fraction of the initial population escapes the decontamination process. Furthermore, it is highly improbable that the number of decimal reductions (log kills) obtained on a high population level could be reached when the initial population level is low. In any case, the outcome is the survival of a low number of pathogenic bacteria on the food surface. For this reason, decontamination may be acceptable when the probability of infection by low doses is low. But it is certainly not a good measure against pathogenic micro-organisms when the probability of infection by low doses is high (e.g. E. coli O157:H7 or other STEC). For such pathogenic micro-organisms, the best protection of consumers is through the application of good hygienic and HACCP principles.

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		Furthermore, as natural prevalence of STEC is low, the only possible trials to judge decontamination efficacy would have to be made after artificial contamination, with no guarantees to reproduce the physiological state and attachment strength of naturally contaminating cells. This point should be specified in introduction. Line 142 : A few lines explaining the words "remove" and "removal" before "surface contamination" should be added to the introduction. Whereas decontamination agents may remove some microbial cells, their effect is mainly to inactivate bacterial cells that are not all detached from the meat surface. Line 147 :It is said that the efficacy of a technique must be assessed by comparison with a control treated with water (lines 57, 147 and 151 among others), in compliance with Regulation 853/2004. Hot water is actually used as a decontamination technique, so it obviously cannot currently be considered as a control. This point should be specified. Line 189:It is one thing to demonstrate a statistically significant reduction in contamination and quite another to accept this amount of reduction. To put it succinctly, a 20% reduction in bacteria during experimentation may not be acceptable in the light of the risks linked to the nature of the microorganisms tested. It is difficult to establish a performance criterion in such a reference system. However, the applicant should develop an argument based on the results obtained with respect to risks. This argument would then be analyzed to decide on its pertinence by the experts responsible for examining the application.
AFSSA	3.2 Summary document	Line 270: It would be useful to be more accurate and add to the "intended use" point the level of performance and action spectrum claimed.
AFSSA	4.1 Identity of the substance(s) and specifications	Line 291: It is important to add an additional point on the chemical reactivity of each ingredient, knowing that this information would need to be related to point 4.4 (Reactions and fate on the treated foods of animal origin after rinsing).
AFSSA	4.3 The treatment and its purpose	Lines 308-309: i. c : Draw up an argument for the relationship between a reduction in contamination and a lower risk. Lines 310 and 311:The aims d and e () should be removed. Lines 315-316: Give more specific information on the relationship between the quantity of product (or substance) and the surface area (or weight) of the foodstuff

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		especially when spraying the carcass.
AFSSA	7. INFORMATION REQUIRED TO ASSESS THE EFFICACY OF A FORMULATED PRODUCT	Line 360: As far as the methodological approach is concerned, for this particular area we cannot currently refer to standardised protocols recognised by the European scientific community. The approach suggested in this document has a number of defects and omissions, such as: - In the Laboratory phase, inoculation is very brief (20 min, as confirmed by appendix A) and not credible. For this flora to grow on the food matrix, a Laboratory simulation would require one night at 4°C-8°C. - Different levels of contamination would be necessary, not just one, to establish a correlation with the risk assessment. - Prior to this simulation of tests in laboratory conditions, it would be useful to provide preliminary information: o On the product's intrinsic activity and its basic action spectrum according to current European standards, o An assessment of the product's ability to maintain this activity in the presence of representative organic media such as proteins and fats, and this at one or more temperatures corresponding to the usage claimed, o An assessment of the product's ability to lower bacterial susceptibility, an evaluation of the stability of this drop in susceptibility and a study of the impact on bacterial susceptibility to antibiotics, o An assessment of the product's impact on the expression of virulence genes, at least from a bibliographical viewpoint. Once these data has been analysed, it will be possible to fully analyse the product's conditions of application and their consequences. Lines 382-383: The end of the sentence should be removed, because at the end of shelf-life, it is not possible to know whether the new detected cells are repaired cells or daughter cells from CFUs that were not detectable (below the detection limit) after

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		application of the decontamination solution.
AFSSA	8. INFORMATION NECESSARY FOR THE EVALUATION OF THE POTENTIAL EMERGENCE OF ANTIMICROBIAL RESISTANCE (AMR)	Lines 437 to 439: This type of research must be carried out even if the product is already used and authorized in the framework of other regulations. Setting aside the fact that conditions of use would probably be different, we need to consider knowledge development. Consequently, the applicant should at the very least justify the fact that further research is not necessary.
AFSSA	8.3 Type and quality of data	Line 511-514: to test susceptibility for antimicrobials and decontamination agents, two types of methods are suggested: determination of the MIC and MBC. It must be noted that MIC and MBC of decontamination agents are not always correlated as shown for instance for Chlorhexidine Gluconate-Containing Mouthwash by McBain et al. 2003. Those authors suggested that, for several studied strains, "growth inhibition and lethality are related to interaction with different targets". Thus if a decontamination agent has for instance an increased MIC and a non-modified MBC, the bacteria in question could be declared as having a "reduced susceptibility". The decontamination agent could consequently be rejected although its MBC is adequate for its intended used, which is to kill bacteria, not to inhibit their growth
AFSSA	APPENDICES	APPENDIX A: Line 770: - Different levels of contamination should be studied, which would be consistent with what is written in line 399. - The conditions of inoculation of microorganisms are not sufficiently representative: prefer a night at 4-8°C to 20 min at an ordinary temperature, Line 774 - The volume of product sprayed should be specified for comparison with the surface area treated. - After contact, the product should be rinsed off with a suitable validated neutralizing agent so as to stop residual activity. This is consistent with line 405. APPENDIX B:

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		Line 811: After treatment, add a rinsing stage with the neutralizing agent validated previously.
AFSSA	DEFINITIONS	Line 920: With regards to resistance, only the expression "antimicrobial resistance" appears in the chapter on definitions and linking this term to conditions of use in practice is quite acceptable. However, in the body of the document, we often find the expression "potential occurrence of acquired reduced susceptibility" which is distinct from the expression "development of resistance to antimicrobials". All these terms relating to "resistance" should be carefully defined and distinction should be made between adaptation to inhibitory concentrations and resistance to killing concentrations of decontamination agents. There are several definitions of resistance in the literature. To avoid confusion between the impact on growth inhibition and the impact on killing of decontamination agents, we suggest as in Lear et al (2002), in the Afssa opinion (Afssa, 2007) and in Cerf at al. (2010), the use of the word "resistance" in the context of micro-organism killing and "tolerance" in the context of adaptation to inhibiting concentrations. Moreover, there is an agreement between EU Member States relating to Biocides directive 98/8/EC in the TNG (Technical Notes for Guidance, in support of annex VI of directive 98/8/EC of the European parliament and the Council concerning the placing of biocidal products on the market – ECB, February 2008 - chapter 6 "Assessment of other unacceptable effects" revised in 2009). Whatever the vocabulary chosen, it must be included in the Definitions section. Lines 926- 933: For the definitions of "co-resistance", "cross-resistance" and "multidrug resistance", it would be useful to refer to the technical Notes for Guidance, in support of annex VI of directive 98/8/EC of the European parliament and the Council concerning the placing of biocidal products on the market . Line 941: As regards "Decontaminating agents", it is written that "These are substances applied to remove or reduce surface contamination"; a definition repeated in point 2, Objective (line 226). Reducing contamination is obviously a consequence of elimination. It would be more accurate to write "remove and/or destroy surface contamination" or "inactivate and possibly remove surface microbial contamination". This definition is to be compared with line 65 defining decontamination as a reduction in the level of microbial contamination of carcasses and with line 83 (+ lines 189-190) introducing another approach, this time the reduction in prevalence and/or number of

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		targeted pathogenic bacteria. In other words, the text needs to be made consistent. Line 946: For the definition of disinfection", it would be useful, to be consistent with other European texts, to refer to European standard EN 14885 (February 2007) "Application of European standards for chemical disinfectants and antiseptics". The term "residue" needs to be defined. There is already a clear and thorough definition in Biocides directive 98/8/EC.
U.S Meat Export Federation	General comments	1. General - Will there be separate guidance issued to specify the residue standards and microbial standards to be applied to imported product that may undergo pathogen reduction treatments (PRT) in accordance with the exporting countries federal requirement or international standards (ex. Codex) versus domestic use of PRT? 2. General – (1) The environmental, toxicological and ecotoxicological effects of PRT application in exporting countries are outside of the measures which can be evaluated on imported product. (2) Further, resistance to therapeutic antimicrobials primarily develops by exposure of organisms to therapeutic antimicrobial compounds themselves, which in reference to imported products occurs in the exporting country. Therefore, this guidance appears to only apply to PRT when applied within the European Union, is this correct? 3. General – Revisions to the Guidance Document make it significantly more difficult to gain approval of novel products due to the shear amount of new research that would need to be funded in order to gain one approval.
U.S Meat Export Federation	1. INTRODUCTION	4. Introduction – Line 162 - The introduction states that it is required that all products be rinsed following PRT application to assure that there is no technological effect on the final product. Must the product be rinsed if research shows that there will be no technological effect on the final product without rinsing? 5. Introduction – Line 193-194 - In plant studies are recognized as the best way to validate efficacy of PRT, are companies permitted to utilize studies performed in other countries or as reviewed by international standard setting bodies? Further, many in-plant studies have been performed and in some countries, these products have been used for a long time. Will data collected from facilities using these products, despite not being run as part of a study with a "non-treated" control, be deemed as acceptable data for review, as it is the best way to validate efficacy in a real production system?

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		6. Introduction – Line 195-196 - How is consumer acceptance to be demonstrated? 7. Introduction – Line 195 – 196 - The current document does not elaborate on the meat/poultry quality data required for approval. In the U.S., for approval of processing aids for red meat, it is required that the quality of the meat is not degraded by the treatment. Therefore, it is required that submissions include thiobarbituric acid (TBA) values and fatty acid profiles for treated and untreated (control) product.
U.S Meat Export Federation	3.2 Summary document	8. Section 3.2 – Line 272 – The document calls for existing authorization in the European Union (EU) and other countries. Would this be authorizations within the EU for other uses? Further, it is recommended that a request for analysis and approvals for the ingredients and treatment from international standard setting bodies be included; Codex Alimentarius, Joint FAO/WHO Expert Committee for Food Additives, Joint FAO/WHO Joint Expert Meetings on Microbial Risk Assessment, and relevant results from ad-hoc FAO/WHO Expert Committees.
U.S Meat Export Federation	5. CONSUMER EXPOSURE ASSESSMENT	9. Section 5, Line 336 -337 – The document requires an estimate of potential daily exposure of the consumer to residues, degradation products and any relevant reaction by-products present in the treated food. However, the document does not specify if exposure is to be based on meat products alone or on cumulative exposure. Many of these PRT products are approved for use in non-meat food products (ex. acetic acid) and U.S. submitters will need to know if estimates of exposure are to be based on cumulative daily intake for all the approved uses of the proposed product or for meat alone. Lastly, is information from international standard setting bodies and third countries permitted?
U.S Meat Export Federation	6. TOXICOLOGICAL AND ECOTOXICOLOGICAL DATA	10. Section 6, Line 342-346 – It is stated that available toxicological and ecotoxicological data on each substance, including its potential degradation products and any identified reaction by-products, should be submitted. Is information from third countries and international standard setting bodies (ex. Codex) acceptable? In many cases, PRT are approved for use as processing aids or direct food additives in other countries or by international standard setting bodies and significant amounts of relevant research has already been conducted. Will references and analyses by international standard setting bodies or other nations be considered where relevant?
U.S Meat Export Federation	7. INFORMATION REQUIRED TO ASSESS THE EFFICACY OF A FORMULATED PRODUCT	11. Section 7 Line 365– The dossier intended to assess efficacy should include full reports of all relevant experiments. Some PRT have a long history of use in multiple countries. The amount of relevant experiments in some cases is insurmountable. It is recommended that the document be clarified to allow for robust, relevant literature reviews. 12. Section 7 Line 372 – The document specifies that the study must include a

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		comparison of the prevalence and/or numbers of the pathogenic microorganisms on the food of animal origin to which the formulated product will be applied and on the untreated control food. Are there certain pathogens, strains of pathogens, or inoculation levels that would be deemed acceptable or unacceptable for evaluation? 13. Section 7 (vi) Line 391-393 – The document specifies that all tests should be performed on a sufficient number of samples, depending on the actual prevalence and/or numbers of the target organisms. Is there a reference or guidance document that will help submitters to determine what is a sufficient number of samples? 14. Section 7 (vii) Line 399-401 – The document specifies that the efficacy of the formulated product must be validated by testing on naturally contaminated foods of animal origin. Please define "naturally contaminated foods of animal origin" and the sample numbers expected. Further, what pathogens of natural contamination are expected? Based on the low prevalence rate of pathogen presence on U.S. products pre-treatment with PRT, a significant volume will be difficult to acquire. 15. Section 7, part xii – Line 471-420 – The document requires that data from facilities using authorized products be submitted. This would require an applicant from the EU to obtain data from processing facilities in other countries and obtain the cooperation of non-EU private facilities. Will there be guidance to facilitate cooperation between countries and/or companies? 16. Section 7 (xii) – Line 424-426 Study designs for efficacy are to take into account different target pathogens and microorganisms, please clarify what the target organisms/pathogens - according to species – are expected in the studies? It is quite possible that different countries or companies would have a different perspective on the appropriate organisms and may require guidance in order to comply with reviewer expectations.
U.S Meat Export Federation	8.1 Pre-market evaluation	17. Section 8.1 – Line 481- 488 - The requirements for a pre-market evaluation for antimicrobial resistance are impossible to meet for any novel treatment that may be proposed. It is required that upstream-downstream sampling be performed and that bacteria isolated from sediment and wastewater plants be examined. Neither this data, nor the potential to develop this data will exist since it is not in use. Further, even for in-use treatments, the requirement would require cooperation of private facilities in other countries. Finally, it is highly improbable that any useful information about the effects of potential discharges on PRT of bacteria in sewage plants could be discerned. Sewage plants have inputs from many sources, have a myriad of trace-levels of

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		household disinfectants, have bacteria coming directly from humans and animals, and have, in most facilities, bacteria and chemicals from surface water runoff. Lastly, very few packing plants in the U.S. utilize sewage plants for wastewater discharge, most have their own waste water treatment plants, making it difficult to obtain enough of the required data for EU facilities that may require such information. 18. Need further recommendations for "novel" products
U.S Meat Export Federation	8.2 Post-market evaluation	19. Section 8.2(iv) 505-506 – The antimicrobial resistance post-market evaluation requires three years of data collection. It is not clear if product can be approved following pre-market evaluation and then post-market evaluation is permitted to begin, where data collection for post-market evaluation would commence. If approval were only to occur after post-market evaluation it is not clear how this data would be obtained if approval were not permitted in advance. Furthermore, if the product is approved in a foreign country, would an exchange of information between countries and/or companies be acceptable?
U.S Meat Export Federation	9. INFORMATION NECESSARY FOR THE EVALUATION OF THE TOXICOLOGICALENVIRONMENTAL IMPACT OF THE SUBSTANCES	20. Section 9 – Line 526-528 - In order to authorize the use of substances for the removal of microbial surface contamination of foods of animal origin, data set and information are required about the conditions of application and release of the substance and eventually by-products or degradation products in the environment. Environmental requirements for PRT approved for use in other countries and by Codex will be different than what is required by the EU. Will these studies need to be conducted in the EU in order to be deemed acceptable? Will they need to be performed by an EU company?
U.S Meat Export Federation	APPENDICES	21. Appendices - Line 752 - The document provides example experimental designs, please clarify the purpose of the example experimental designs in the three appendices. Will an applicant need to perform the protocols provided in the appendices? If an applicant conducts such an efficacy test, will that single test be sufficient? Are pre-existing studies designed in a way different from the studies in appendices considered acceptable? 22. Appendix A - Line 753 - The example experiments for determining efficacy specify treatment with water only versus treatment with water and an additive. The example experiments should be revised to include pre-treatment measurements, as well as including a non-treated control group. For example, treatment (water or PRT + water) may increase prevalence relative to an untreated control group due to cross-contamination. The inclusion of a pre-treatment control group is standard in peer reviewed research. 23. Appendix C – Line 865 and Line 899 - The appendix examples suggest a

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		statistical test for determining efficacy have at least a 50% reduction in prevalence and for a 0.5 log 10 CFU/gram reduction in mean concentration. Does this mean that a treatment that gives a <50% reduction in prevalence or a <0.5 log 10 CFU/gram reduction would not be accepted? If so, what is the reasoning behind these values? Reductions of less are still of a significant health benefit to consumers?

APPENDIX B

The text below is from the EFSA website of the public consultation:

Public consultation on the revision of the joint AFC/BIOHAZ guidance document on the submission of data for the evaluation of the safety and efficacy of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption

Deadline: 22 February 2010

EFSA's Biological Hazards (BIOHAZ) Panel has published for public consultation a revision of the joint guidance document of the BIOHAZ and former AFC panels for the submission of applications on the substances to be used for removing microbial contamination from the surface of foods of animal origin.

The guidance includes data and examples of study designs for the evaluation of these substances with regard to their safety for consumers and the environment and their effectiveness in decreasing the level of microbial contamination. The guidance also indicates how the evaluation of the possible development of antimicrobial resistance triggered by decontamination agents should be carried out.

The information and data requested in this guidance concerning toxicological aspects (chapter 6) reflect what was previously indicated in the joint AFC/BIOHAZ guidance document published in 2006.

Interested parties are invited to submit written comments by 22nd February 2010. Please use exclusively the electronic template provided with the documents to submit comments and refer to the line and page numbers. Please note that comments submitted by e-mail or by post cannot be taken into account and that a submission will not be considered if it is:

- submitted after the deadline set out in the call
- presented in any form other than what is provided for in the instructions and template
- not related to the contents of the document
- contains complaints against institutions, personal accusations, irrelevant or offensive statements or material
- is related to policy or risk management aspects, which is out of the scope of EFSA's activity.

EFSA will assess all comments from interested parties which are submitted in line with the criteria above. The comments will be further considered by the EFSA BIOHAZ Panel and taken into consideration if found to be relevant.

Published: 22 January 2010