DOWNLOAD PDF USDA/FDA ANNOUNCEMENT ON NITRITES AND RELATED ISSUES

Chapter 1 : Yes, bacon really is killing us | News | The Guardian

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Learning Objectives After completing this section, you will be able to Describe the U. EPA believes that exposure below this level is not expected to cause significant health problems. All public water supplies must abide by these regulations. Given present technology and resources, this MCL is also a level to which water systems can reasonably be required to remove this contaminant should it occur in drinking water. Once a water source is contaminated, the costs of protecting consumers from nitrate exposure can be significant. Nitrate is not removed by conventional drinking water treatment processes, and Its removal requires additional, relatively expensive treatment units [EPA]. This intake appears to be safe for healthy neonates, children, and adults. EPA has set an RfD of 0. If these standards are met, water is considered safe for most healthy individuals. However, although not often reported, bottled water outbreaks do occur. More information on bottled water can be found at http: As a preservative and color fixative, with or without sodium nitrite, in Smoked, cured sablefish Smoked, cured salmon Smoked, cured shad so that the level of sodium nitrate does not exceed parts per million ppm and the level of sodium nitrite does not exceed ppm in the finished product. As a preservative and color fixative, with or without sodium nitrite, in meat-curing preparations for the home curing of meat and meat products including poultry and wild game , with directions for use which limit the amount of sodium nitrate to not more than ppm in the finished meat product and the amount of sodium nitrite to not more than ppm in the finished meat product. The food additive potassium nitrate may be safely used as a curing agent in the processing of cod roe, in an amount not to exceed ppm of the finished roe. This includes inspection for required labeling of meat products when substances such as sodium nitrate are used in meat packaging [USDA]. Environmental Standards The current water standard for nitrate is based on levels considered low enough to protect infants from methemoglobinemia. Some published results suggest a possible association between nitrate exposure during pregnancy and human malformations [Croen et al ; Brender et al ; Brender et al]. However, a review of the toxicology in relation to possible adverse effects on reproduction and development offers no evidence for teratogenic effects attributable to nitrate or nitrite ingestion [Manassaram et al ; Huber et al]. The present maximum contaminant level appears to adequately protect even sensitive populations from nitrate-induced toxicity [Fan and Steinberg ; EPA]. EPA concludes that the evidence in the literature showing an association between exposures to nitrate or nitrites and cancer in adults and children is conflicting [EPA , ,]. Key Points The current water standard for nitrate is based on protection of infants from methemoglobinemia.

Chapter 2 : USDA ERS - Interactive Charts and Highlights

USDA/FDA announcement on nitrites and related issues: hearing before the Committee on Agriculture, House of Representatives, Ninety-sixth Congress, second session, September 16, [United States.

Page 54 Share Cite Suggested Citation: Risk Assessment in the Federal Government: Managing the Process Working Papers. The National Academies Press. Describe the chemical and its uses. Nitrogen exists in nature in various forms one of which is nitrate. Nitrites are chemicals that form when living systems act upon nitrate salts, which are widely distributed in soil, plant s, and cancer, or upon n i trogen in o ther forms. Nitrite inhibits the growth of various microorganisms found in foods, including Clostridium botulinum. It also helps to maintain the typical reddish color of cured meats, inhibits the development of rancidity in meat and fish, and may contribute to the flavor of cured products. It is currently added to meats and fish primarily as an antimicrobial. Approximately 25Z of all meats consumed by the U. Describe how the question of risk was elevated to the agency level. There are two aspects related to the risks of nitrite inge. This case study describes assessment procedures and summarizes issues and interpretations raised by others, but it is not intended to present independent positions or interpretations on either scientific or policy matters. The case has been reviewed by individuals outside the s tudy pro j ec t who are d i rec t ly f ami 1 far wi t h t he f ede ra 1 analyse s and decisions described; however, responsibility for the paper rests with the author, and it does not necessarily reflect the judgment of the Committee on the Institutional Means for Assessment of Risks to Public Realtl, or the National Research Council. It has not been sub- jec ted to internal review procedures the t app ly to report s prepared by NRC commi t tees. Earlier findings had also indicated that nitrosamines could form in the body fat lowing inges tion of nitrite. In , ache t? Sl A was petitioned to ban or greatly reduce the use of nitrite. The petition was denied. Based on additional evidence of the presence of nitrosamines in bacon, the Secretary of Agriculture appointed an advisory Expert Panel on Nitrites ant Nitrosamines. Before a regulation can be established the additive must be shown to be safe and functional for its intended uses i. Ibis provision is commonly known as the Delaney Clause. I f the evidence is not sufficient to prove that the substance is carcinogenic out does raise substantial unresolved ques tions about its safety, the general safety clause o f the act 21 U. The requirements for revoking approval of a food additive are not as demanding under the general safety clause as under the Delaney Clause. FDA does not have the burden of proving that a substance causes cancer or that it is otherwise unsafe; FDA has only to present new evidence that raises a subs tantial safety question. Because prior sanctioned substances are not covered by the definition of "food additive, " the provis ions of the Food Additives Amendment, including the Delaney Clause, do not apply to them. The three laws under which prior sanctions were granted provide, however, that the public is to be protected from adul- terated food products. They state that food is adulterated if "it bears or contains any poisonous or deleterious subs tance which may render it in jurious to health. While FDA has primary responsibility for approving the use of substances identified as food additives, US] A has the additional respon- sibility to determine that an FDA-approved additive may be used in meat and poultry products. USDA also restricts and monitors the use of approved additives to assure that requirements for safe use are met. No written report submitted. Interagency Woricing Group I. AWO on nitrite meets. The Attorney General found that there was no legal basis for a ohaseout and. A number of bills are intro- duced in Congress to prevent the agencies from banning or phasing out nitrite. NAS releases final report confirming that nitrite per se is not a carcinogen but that it may contribute to formation of carcinogenic nitrosamines. Paul Newberne, a senior pathologic t at MIT, which showed that nitrite caused a statistically significant increase in the number of lymphoid tumors in rats. In tale large lifetime s tudy conducted for the Food and Drug Administration FBA , sodium nitrite was administered to groups of approximately 68 male and 68 female Sprague-0awley rats under a variety of conditions. For these groups, an agar-based semisynthetic diet was used. For groups 9 to Il. Groups 1 through 16 were exposed prenatally, simile groups 17 and 18 were exposed at 21 days. The

incidence of this abnormal i ty in nitrite-created animals, however, was greater To performed the initial analysis? To what extent were the resut ts presented quantitatively? What factors influenced the degree of quantification? Row was uncertainty described in reaching the final inter- pretations? Were crucial assumptions made explicit? Assumptions that had to be made were listed: How were qualitative factors dealt with? This discussion did not empha- size the uncertainty of extrapolating from animals to man but instead served to refute arguments that have been made against this use of animal tests. The numbers in parentheses are the estimated lifetime cancer risks per 10, population. Ibis problem awaited scientific critique and eventually led to the refutation of the FDA conclusion. Mat qualitative factors affected the weighting of data? Were such criteria explicit and in accord with any general guide- 1 ines? Allis is consistent with IRLO guidel ines. Describe any internal, internal advisory, and external scientific review of the initial analysis. Apparently, there was no internal or external peer review of the ini tial analys is prior to ache Commiss loner informing the Secretary of HEW of the plan to phase out nitrite. At the same time, the study results were sent to outside reviewers. The following criticisms were made: The dispari ty be tween the two series of diagnoses involved the differentiation of lymphomas from extramedul lary kematopoiesis, plasmacytosis, or histiocytic sarcoma. Newberne, [the scientist who conducted the original study] with a significantly in- creased incidence in the total combined treated groups as compared to combined controls. Thi s ra te 0 f 1yrephoma incidence is similar to that usual ly seen spontaneous ly in Sprague-Dawley rats. UAREP pathologic ts did report a greater than 1: However, after statistical analysis and careful review by the IAWG, no demonstration could be found that the increased incidences of these tumors were induced by the inges tion of sodium nitrite. What other issues arose concerning scientif ic data and their use? Briefly describe d issenting opinion. Is the substance subject to past or possible future regulatory actions in other programs? If so, did the program office coordinate with other agencies or programs? The Ad Hoc Working Group felt the data were insufficient to derive such an es timate. It seems clear that the risk assessment was performed after the decision to regulate had been made. Historically, both the Commissioner of FDA and the Assistant Secretary of Agriculture at that time believed that nitrite should be reduced based on the nitrosamine potential. Thus, when the tata apparent ly indicating a direct carcinogenic effect emerged, the premise upon which nitrite could be removed from food was obtained and led immediately to the development o f regulatory strategies. Were there variations in the assumptions used? Were these Two risk assessments have been performed by FDA: The second estimate was approximately 9Z of the original est imate. Despite the fact that the major Elaw in the inter- pretation of the study stemmed from differences in pathologic diagnoses that cannot be addressed by inference guidelines, there were many other scientific issues that were not appropriately cons idered in the initial assessment of risks done by IDA. Adherence to comprehensive guidelines would have required that these issues by looked at more carefully and be addressed in the risk assessment documents Such consideration may have led to a more intense peer review of the study and its interpretation by FDA. Vigorous peer review did not enter into the process until the decision to regulate had already been made. Normal methods of FDA review were not followed for reasons that, at the time, appeared justifiable. FDA contracted for this study. Also, GAO recom- mended that research guidelines should be developed for design, data-recording and reporting, and statistical evaluation for carcinogenicity assays. A major consideration leadin. Newberne and his institution--MIT. US] A and FDA do not have a formal written pa licy for evaluating sc ientific information concerning the safety of food additives. There is an informal review process that is supposed to identify the strengths and weaknesses of the data and the possible regulatory alternatives. Bureau of Foods is responsible for scientific evalua- tion. If cancer is involved, the Division of Toxicology begins the review. The study is then forwarded to the Cancer Assessment Committee. If the Committee members feel that a substance has major scientific, economic, and regulatory significance, they will recom- mend formation of an interagency working group IAWG to evaluate scientific meri t. Assessments were done by four different groups: The credibility of the initial assessment was low. Scientists within the agency who normally review such data and who were not involved in the review of ni trite felt uncomfortable with the caliber of individuals reviewing the study. Subsequent review of the study

revealed many flaws in tie data, casting further doubt on the conclusions drawn in the original assessment. The credibility of the second review was not a major issue as this was an internal document looking at the broader issues of nitrosamine formation as well as nitrite carcinogenicity. The final results of the TANG deliberations were released two years after its review began. These results were supported by an independent pathology review. Thus, it had more credibility than the first assessment. What was the extent of diversity of policy orientations within the assessment group?

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Chapter 3 : USDA ERS - Biotechnology

The item CAST-related excerpts from U.S. House of Representatives hearing on USDA/FDA announcement on nitrites and related issues represents a specific, individual, material embodiment of a distinct intellectual or artistic creation found in Brigham Young University.

Pinterest Prosciutto di Parma has been produced without nitrates since The madness, in his view, is that it is possible to make bacon and ham in ways that would be less carcinogenic. The most basic way to cure any meat is to salt it â€" either with a dry salt rub or a wet brine â€" and to wait for time to do the rest. But the real reason they reject it is cost: Technically, processed meat means pork or beef that has been salted and cured, with or without smoking. A hard stick of cured salami is. The health risk of bacon is largely to do with two food additives: It is these that give salamis, bacons and cooked hams their alluring pink colour. Saltpetre â€" sometimes called sal prunella â€" has been used in some recipes for salted meats since ancient times. In earlier centuries, bacon-makers who used saltpetre did not understand that it converts to nitrite as the meat cures. It is this nitrite that allows the bacteria responsible for cured flavour to emerge quicker, by inhibiting the growth of other bacteria. But in the early 20th century, the meat industry found that the production of cured meats could be streamlined by adding sodium nitrite to the pork in pure form. In trade journals of the s, the firms who sold nitrite powders to ham-makers spoke quite openly about how the main advantage was to increase profit margins by speeding up production. Nitro-chemicals have been less of a boon to consumers. In and of themselves, these chemicals are not carcinogenic. After all, nitrate is naturally present in many green vegetables, including celery and spinach, something that bacon manufacturers often jubilantly point out. When nitrates interact with certain components in red meat haem iron, amines and amides , they form N-nitroso compounds, which cause cancer. The best known of these compounds is nitrosamine. Any time someone eats bacon, ham or other processed meat, their gut receives a dose of nitrosamines, which damage the cells in the lining of the bowel, and can lead to cancer. You would not know it from the way bacon is sold, but scientists have known nitrosamines are carcinogenic for a very long time. More than 60 years ago, in , two British researchers called Peter Magee and John Barnes found that when rats were fed dimethyl nitrosamine, they developed malignant liver tumours. By the s, animal studies showed that small, repeated doses of nitrosamines and nitrosamides â€" exactly the kind of regular dose a person might have when eating a daily breakfast of bacon â€" were found to cause tumours in many organs including the liver, stomach, oesophagus, intestines, bladder, brain, lungs and kidneys. In the years since, researchers have gathered a massive body of evidence to lend weight to that assumption. In , to take just one paper among hundreds on nitrosamines and cancer, two American epidemiologists found that eating hotdogs one or more times a week was associated with higher rates of childhood brain cancer, particularly for children who also had few vitamins in their diets. In , Parma ham producers in Italy made a collective decision to remove nitrates from their products and revert to using only salt, as in the old days. For the past 25 years, no nitrates or nitrites have been used in any Prosciutto di Parma. Even without nitrate or nitrite, the Parma ham stays a deep rosy-pink colour. The sugar conspiracy Ian Leslie Read more Slow-cured, nitrate-free, artisan hams are one thing, but what about mass-market meats? But there have always been recipes for nitrate-free bacon using nothing but salt and herbs. John Gower of Quiet Waters Farm, a pork producer who advises many British manufacturers of cured meats, confirms that nitrate is not a necessary ingredient in bacon: It could have happened 40 years earlier. The US meat industry realised it had to act fast to protect bacon against the cancer charge. The first attempts to fight back were simply to ridicule the scientists for over-reacting. This was an outrageous fabrication. But soon the meat lobby came up with a cleverer form of diversion. The scientific director of the AMI argued that a single cup of botulism would be enough to wipe out every human on the planet. So, far from harming lives, bacon was actually saving them. In , the FDA and the US Department of Agriculture gave the meat industry three months to prove that nitrate and nitrite in bacon caused no harm. Instead, the argument was made that nitrates and nitrites were

utterly essential for the making of bacon, because without them bacon would cause thousands of deaths from botulism. The first move is: These meat researchers published a stream of articles casting doubt on the harmfulness of nitrates and exaggerating the risk from botulism of non-nitrated hams. Does making ham without nitrite lead to botulism? If so, it is a little strange that in the 25 years that Parma ham has been made without nitrites, there has not been a single case of botulism associated with it. Almost all the cases of botulism from preserved food â€" which are extremely rare â€" have been the result of imperfectly preserved vegetables, such as bottled green beans, peas and mushrooms. The botulism argument was a smokescreen. The more that consumers could be made to feel that the harmfulness of nitrate and nitrite in bacon and ham was still a matter of debate, the more they could be encouraged to calm down and keep buying bacon.

Chapter 4 : Sodium nitrate in meat: Heart disease risk factor? - Mayo Clinic

CAST-related excerpts from U.S. House of Representatives hearing on USDA/FDA announcement on nitrites and related issues Author: Council for Agricultural Science and Technology.

Chapter 5 : USDA National Organic Program

The U.S. Department of Agriculture (USDA) is made up of 29 agencies and offices with nearly , employees who serve the American people at more than 4, locations across the country and abroad. We provide leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on public policy, the best.

Chapter 6 : Borlaug Fellowship Research Priorities by Country | USDA Foreign Agricultural Service

The Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) take the threat of botulism so seriously that nitrites are required to call a meat product "cured." Without nitrites, a product must be labeled as "uncured" and "no nitrate or nitrite added.".