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ONE HUNDRED NINTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

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March 30, 2006

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BUD ALBRIGHT, STAFF DIRECTOR

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

We ask you to order the Food and Drug Administration (FDA) to rescind its GRAS (generally regarded as safe) determinations regarding the use of carbon monoxide to color meat and fish until such time as notice and comment rulemaking can determine whether such practices, under existing conditions of refrigeration and labeling and existing consumer practices, are safe for American consumers. If you choose not to order the FDA to take immediate action, we ask that you undertake an immediate public information campaign to inform consumers that they cannot rely on color to ascertain the safety of meat and fish. Such a campaign should contain cautions such as never under any circumstance consume meat or fish that exceeds its "use by" date; never remove meat and fish from their dated packaging before use; and, if consumers have problems with reading the packages or smelling the contents, to seek help before consuming such products.

On February 9, 2006, Representatives Dingell and Stupak sent the attached letter to FDA Commissioner von Eschenbach detailing concerns regarding the decisions to permit meat of unknown age and safety to be displayed as red and therefore wholesome. While FDA has not found time to respond to the concerns raised in the February 9 letter, it did find time on February 27, 2006, to hold a press conference to address public indignation over the FDA decision. Unfortunately, several statements by the two FDA representatives, Dr. Laura Tarantino, Director of the Office of Food Additive Safety, and Ms. Susan Bro, a public relations official assigned to the Commissioner's Office, were helpful to the meat industry, but not helpful to consumers.

Meat that is packaged with the CO captured within the packaging until it is opened will retain a fresh, appetizing appearance indefinitely under almost any storage conditions. The attached pictures are of meat whose "use by" date was in October, and meat packaged with and without CO and left at room temperature for 27 hours. Clearly the coloring of each package that contains CO is deceptive in that the meat appears safe yet is entirely spoiled.

At the February 27th press conference, Dr. Tarantino plainly stated: "I think one of the issues is that color probably is not a major or particularly good indicator of spoiled meat." That is certainly the case after FDA's decision. But what most every American consumer knows and Dr. Tarantino knew or should have known is that color has been the principal basis for consumer determinations of the quality and safety of meat. Not only is this fact recognized by multiple marketing studies by the meat industry itself, it is clearly the only reason that the industry sought the GRAS determination. Nowhere is it alleged that placing meat in a sealed atmosphere containing CO has any purpose other than to assure that the meat appears fresh regardless of its age.

This could have significant consequences. The industry presentations to FDA and the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) were made on an *ex parte* basis behind closed doors. It appears from FDA and FSIS statements that the industry presented evidence that toxins would not attach to meat kept at 38-42 degrees F during an interval of 28 to 42 days depending on the cut. What Dr. Tarantino should have known, however, (at least by the time of the news conference because it is referenced in petitions before the FDA) is that meat is not stored at a constant 38-42 degrees. Most people understand this from common experience. One study stated: "Temperature abuse is common throughout the distribution and retail markets, with temperature in 21% of household refrigerators often higher than 10 degrees (C) (50 degrees F). Recent data suggested that 33% of retail refrigerated foods were held in display cases above 7 degrees C (45 degrees F) and 5% were held above 13 degrees C (55 degrees F). Temperatures were even higher in southern market regions. Serious microbial stability problems exist because of the frequency of temperature abuse."

Further, whatever incentive existed to assure adequate refrigeration of meat because of the fear of economic loss associated with "browning" was diminished by the FDA decision. Now that the consequences of poor handling of meat will not be obvious, such mishandling can be expected to increase.

Who might be hurt? The population least able to protect itself against this FDA-approved deception is the most vulnerable to the potential illnesses from bad food. The Centers for Disease Control and Prevention has identified the elderly (along with infants and the immunocompromised) as at the highest risk for illness and death from foodborne illness. It is precisely this group that is mostly likely to be losing a meaningful sense of smell, and is least able to read the often obscure labeling.

Dr. Tarantino advises that smell is a better indicator than color of spoilage in meat. But the National Geographic Survey (NGS), in a seminal work involving 1.2 million subjects, found that chemical exposure, pregnancy, and head injury as well as colds and flu can cause permanent loss of smell but overwhelmingly such loss occurs as we age. As one article by prominent nutritionists noted after reviewing the NGS findings, "the decline in sensitivity to the odor with age is large enough to render the odor useless as a warning for about half of the elderly population."

Also, because some deterioration of eyesight is virtually universal after age 40, it is precisely those Americans that are least able to rely on a sense of smell that are also likely to be victimized by the lack of meaningful labeling standards. Both Dr. Tarantino and Ms. Susan Bro dismissed press conference questions regarding inadequate labeling by noting that it is the Department of Agriculture's responsibility to assure that meat is properly labeled. Apparently, they believe the legibility of the labeling was not their problem even though FDA's decision made prominent "use by" labeling the consumer's only defense against unsafe meat.

This is no idle concern. A trip to any supermarket reveals that the labeling on meat products often appears to be deliberately illegible. Certain of the pre-packaged products use low-resolution ink jet printing on the film packaging itself to "inform" the consumer of the end date. Such printing is not visible to someone with 20/20 vision unless the light hits it at a certain angle. Other packages print the "use by" in 8-point type or less combined with other information that is not relevant to product safety such as weight.

Given these facts, we urge you to order FDA to rescind its acceptance of the use of carbon monoxide to color meat and fish until a full and public process can be undertaken and, if CO is ultimately allowed, until labeling is strengthened and clarified. If you refuse, you should at least order an aggressive public campaign to tell consumers they can no longer trust what their eyes are telling them about the suitability and safety of packaged meat and fish.

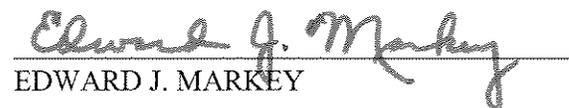
Because the misleading use of carbon monoxide continues, we ask that you examine these matters and respond to us by Wednesday, April 12, 2006. If you have any questions regarding these requests please contact one of us, or have your staff contact David Nelson of the Committee Democratic staff at (202) 226-3400.

Sincerely,


JOHN D. DINGELL


HENRY A. WAXMAN


BART STUPAK


EDWARD J. MARKEY

Attachments

cc: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Nathan Deal, Chairman
Subcommittee on Health

The Honorable Mike Johanns, Secretary
Department of Agriculture

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U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

JOE BARTON, TEXAS
CHAIRMAN

February 9, 2006

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Andrew C. von Eschenbach, M.D.
Acting Commissioner
Food and Drug Administration
5600 Fisher Lane, Room 1555
Rockville, Maryland 20857

Dear Dr. von Eschenbach:

We understand that a series of related decisions by the Center for Food Safety and Applied Nutrition (CFSAN) apparently permits the use of carbon monoxide to alter the color of meat and fish to make those substances appear edible beyond the time when they may decompose sufficiently to be contaminated by one or more dangerous toxins.

A review of Food and Drug Administration (FDA) responses to GRAS (generally recognized as safe) notices by interested companies indicates that the FDA has apparently decided that (1) it can ignore its own regulations, (2) that it can issue potentially dangerous determinations without public hearings or any form of notice and comment procedure, and (3) that it will accede to the requests of meat and fish packers and packaging manufacturers seeking to extend the shelf life appeal of meat and fish regardless of a potential impact on the public health.

Our review of the very limited public documents and other materials (obtained by interested parties under the Freedom of Information Act (FOIA) and provided to us) raises serious questions that require your prompt attention:

1. What is the reason to believe that this artificial coloration of meat and fish will not fool consumers to their detriment? The data attached to GRN 000083 ("Pactiv" notification) and GRN 000143 ("Precept Foods" notification) reveal no arguments, much less definitive science, to suggest that consumers will not be fooled by artificial coloring of meat products. In fact, that is the stated purpose of their petitions. The FDA response to GRN 000167 (Tyson notification) suggests that CFSAN reviewed no data in that case that would show that consumers can distinguish meat colored to look fresh but of potentially dangerous age from meat that is in fact fresh.

2. The Precept Foods notice argues that end dating will be sufficient notice to consumers of meat in danger of spoiling. None of the documents obtained under FOIA associated with that notice, however, purport to have measured the extent to which consumers are guided by end dating when purchasing meat, a commodity that has typically been purchased based on appearance. Nor is there any indication in the FDA response to any of the notices of an FDA requirement regarding the type, size, color, or placement of “use or freeze by” information on the package. Does the FDA possess and did it consider scientific studies on how consumers distinguish good meat from that which is going bad? If not, why not? Does the FDA have requirements that specify how prominent critical safety information such as the end date must be displayed on packaged meat and fish? If not, why not?
3. Your CFSAN scientists apparently think there is no danger to the public health in permitting the packagers to disguise the degradation of meat and fish. What is the basis for that belief? Please provide all relevant documentation including all internal notes or other memorandum where the issue of disguising the appearance of meat and fish was considered.
4. A plain reading of 21 CFR 173.350(c) appears to categorically prohibit the use of carbon monoxide on “fresh meat products.” Is this prohibition no longer operative? Please explain whether the FDA now disagrees with its own regulation and, if so, why it has not addressed the matter through notice and comment rulemaking.
5. Given that the European Union has banned the use of carbon monoxide on meat and fish products, why does the FDA maintain that such use is “generally recognized as safe”?
6. In a Citizen’s petition filed November 15, 2005, Kalsec argues that neither FDA nor the Food Safety and Inspection Service (FSIS) has ever before approved a color additive for meat precisely because it promotes deception by making meat appear fresher than it is, thus violating Section 721 (b)(6) of the Act and 21 CFR 379e (b)(6). What is the basis for CFSAN’s disregard of both the statutory and regulatory prohibition of disguising meat by artificial coloration with carbon monoxide?
7. Please provide all documents including notes and memoranda relating to all contacts with FSIS personnel regarding GRN000143.
8. The use of carbon monoxide on fish is discussed in GRN 000015. Carbon monoxide is used as an ingredient in “tasteless smoke” which has alleged preservative properties for treating tuna before freezing and thus is not purely employed for its ability to disguise degradation. But the potential for such disguised spoilage in a food that is often eaten raw is of concern. What steps has the FDA taken to assure that fish sellers have not relied on its GRAS notice responses to treat packaged fish with carbon monoxide to make it appear to be fresher than it is?

Dr. Andrew von Eschenbach

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9. Should the FDA require that the presence and purpose of carbon monoxide be prominently labeled so consumers can be aware of what they are buying?

FDA is first and foremost charged by Congress with protecting the public health and the safety of the food supply. But the FDA's decisions to not object to GRAS notices regarding the use of carbon monoxide on meat or fish products ignore those mandates. Given the lack of discernible consumer benefit and the obvious increase in risk to consumers of meat and fish from these decisions, we request that you withdraw the FDA response to GRAS notices GRN 000167, GRN 000143, and GRN 000083. And if the FDA believes that it can demonstrate a favorable risk/benefit ratio on the question of the application of carbon monoxide to color fresh meat and/or fish, then the FDA should go to notice and comment rulemaking to acquire the authority to permit such usage.

Thank you for your attention to this public health matter and to our concerns. With regard to questions and related document requests made in this letter, we would appreciate your responses no later than the close of business, Thursday, February 23, 2006. If you have any questions regarding this request, please have your staff contact David Nelson, Minority Investigator/Economist with the Committee on Energy and Commerce, at (202) 226-3400.



JOHN D. DINGELL
RANKING MEMBER

Sincerely,



BART STUPAK
RANKING MEMBER
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS

CC: The Honorable Joe Barton, Chairman
Committee on Energy and Commerce

The Honorable Ed Whitfield, Chairman
Subcommittee on Oversight and Investigations

Dr. Richard Raymond, Under Secretary for Food Safety
Department of Agriculture