DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

June 29, 1979

William B. Schultz, Esquire
Public Citizen Litigation Group
Suite 700
2000 P Street, N.W.
Washington, D.C. 20036

Re: Petition to Declare Nitrites in Bacon a Color Additive, Docket No. 79P-0077.

Dear Mr. Schultz:

This letter responds to the citizen petition that you filed with the Food and Drug Administration (FDA) on March 12, 1979, on behalf of five petitioners: Public Citizen, the Center for Science in the Public Interest, the Community Nutrition Institute, Claudia Silverman, and Sidney M. Wolfe.

I. Introduction

Your petition asks the agency to declare that nitrites in bacon[1/] are a "color additive" within the meaning of section 201(t)(1) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. §321(t)(1), and that nitrites may not be used in the production of bacon unless bacon manufacturers have met the requirements applicable to color additives under section 706 of the Act, 21 U.S.C. §376.

Your petition raises difficult issues of fact and statutory construction. Having carefully considered those issues, the agency has tentatively concluded that nitrites in bacon "impart" color within the meaning of section 201(t)(1) of the Act but qualify for the exception to the "color additive" definition for substances used (or intended to be

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1/ The term "nitrites" will be used in this letter, as it was in your petition, to refer to potassium nitrite, potassium nitrate, sodium nitrite, and sodium nitrate. We note, however, that current United States Department of Agriculture regulations provide only for the use of potassium and sodium nitrite in bacon, not potassium or sodium nitrate. See 43 FR 20992-5 (May 16, 1978).

79P-0077

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used) solely for non-coloring purposes. Your petition is therefore denied. This matter will not be finally resolved, however, until we complete the rulemaking discussed below. This letter sets forth the reasons underlying the agency's tentative conclusions.

II. Discussion

The key factual issue raised by your petition is whether nitrites "impart" color to bacon within the meaning of the statutory definition of "color additive."[2/] We conclude tentatively that nitrites do, as you contend, impart color to bacon.[3/] The chemical process by which we

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2/ Section 201(t)(1) of the Act, 21 U.S.C. §321(t)(1), provides:

"(t)(1) The term "color additive" means a material which -

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring."

3/ The conclusion we have reached in response to your petition must be implemented by rulemaking. Our preliminary conclusion that nitrites "impart" color to bacon will be put at issue (and be finally resolved) in that rulemaking because it reflects a change from the agency's longstanding position that nitrites in bacon "fix" rather than "impart" color. If our preliminary conclusion changes as a result of comments received in the rulemaking, the conclusion that nitrites in bacon are not properly regulated as a "color additive" would, of course, not be affected.

think color is "imparted" is explained in the appendix attached to this letter. For the purpose of considering the legal issues raised by your petition, we will assume (although we have not finally decided) that nitrites impart color to bacon.

A substance that imparts color when added to food is a "color additive" unless FDA determines by regulation that the substance "is used (or intended to be used) solely for a purpose or purposes other than coloring." 21 U.S.C. §321(t)(1). The color additive status of nitrites in bacon thus turns on whether nitrites in bacon qualify for this exception to the definition. The agency concludes in response to your petition that nitrites do qualify for this exception to the "color additive" definition. FDA will initiate rulemaking in the near future to implement that conclusion as to bacon and other products similarly situated.4/

The agency's decision on your petition draws upon, and is consistent with, both the purposes underlying the Color Additive Amendments of 1960 (CAA) and the agency's historical practice of construing the exception clause in section 201(t)(1), including the term "solely," in a reasonable way that avoids anomalous and clearly unintended consequences. In reaching its conclusion, the agency assumes that, as you suggest, manufacturers desire the coloring effect of nitrites in bacon,5/ but the agency rejects your literal application of the term "solely" to that fact.

4/ FDA has not had occasion until now to consider whether nitrites in bacon and in other products similar in relevant respects are excepted from the definition of "color additive" (and thus should be the subject of a regulation so excepting them), because FDA has until now considered the color effect of nitrites in bacon to be a color "fixing" rather than a color "imparting" effect. Only with this tentative change in position on the threshold factual question does it become necessary for the agency to consider whether nitrites in bacon are excepted from the "color additive" definition.

5/ It should be noted that in its comment on your petition the American Meat Institute ("AMI") denies that coloring is any longer an "intended" effect of nitrites in bacon: "[I]t is clear that the intended use of nitrites in bacon is for purposes other than coloring." (AMI Comment at 7).

To understand the proper application of section 201(t)(1) to nitrites in bacon, it is necessary to keep sight of the unusual, perhaps unique, set of facts that bear upon the legal status of nitrites. Although nitrites have a coloring effect when added to bacon, the clearly predominant purpose for adding nitrites to bacon (as reflected by the amount required to accomplish it) is preservation: about 120 parts per million (ppm) of nitrite is required to preserve bacon (see 43 FR 20992-5); only 10-30 ppm is required to color it. Though, as noted, the agency assumes for present purposes that manufacturers desire the coloring effect of nitrites in bacon, that effect is an unavoidable result of the use of nitrites to preserve and is thus clearly subordinate to it: if a manufacturer uses nitrites to preserve, it must accept the color effect whether desired or not. And, no manufacturer currently uses nitrites solely to color bacon.

Furthermore, nitrites have been used in bacon at the levels necessary for preservation for many years; and this use was approved by the United States Department of Agriculture (USDA) prior to enactment of the Food Additives Amendment (FAA) in 1958. When Congress enacted the FAA, it recognized such "prior sanctions" and excepted prior-sanctioned substances from the definition of "food additive" (see section 201(s)(4) of the Act). The purpose of this exception was to permit the continued use of prior-sanctioned substances, such as nitrites in bacon, without any further demonstration of safety. The prior sanction for nitrites in bacon has been judicially recognized. Public Citizen, et al. v. Foreman, et al., No. 78-1068 (D. D.C., February 5, 1979).

An awareness of these facts is crucial to a proper application of the "color additive" definition in this case because they are responsible for the anomalous and unintended impact a literal approach would have on the legal status of nitrites in bacon. If the statute were read literally, as you request, to require regulation of nitrites in bacon as a "color additive" (on the theory that it is not used "solely" for non-coloring purposes), the CAA would have either (1) the unintended effect of completely undoing the prior sanction that Congress had recognized just two years before (making the entire use of nitrites in bacon hinge on the approvability of the clearly and objectively subordinate and unavoidable "color additive" use under section 706 of the Act); or (2) the absurd effect of subjecting the subordinate (10-30 ppm) aspect of nitrite use to section 706 while leaving the

predominant (120 ppm) aspect untouched and, presumably, still prior-sanctioned.[6] It is not clear to the agency which of these consequences would flow as a matter of law from the literal interpretation offered in your petition, but neither would comport with the congressional purpose in enacting the FAA and CAA or with sound public policy.[7] If the statute permits a reasonable construction that satisfies congressional purposes and sound public policy while avoiding such anomalous consequences, that construction should be adopted.[8]

Congress had two specific objectives when, in enacting the CAA, it adopted the broad definition of "color additive" (qualified only by the exception for substances used "solely for a purpose or purposes other than coloring") and excepted "color additives" from the food additive definition (21 U.S.C. §321(s)(3)): (1) It wanted to establish comprehensive lists of colors that would be subject to uniform criteria of admissibility (hence, it dropped the special provisions in the Act for coal-tar colors and provided no exception for generally recognized as safe (GRAS) or prior-

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6/ It is not, of course, just nitrites in bacon for which these unintended outcomes would be possible, but all processed, red meat products (e.g., bologna, processed ham, etc.).

7/ In addition to portending odd consequences for the legal status of nitrites in bacon, your literal interpretation of the term "solely" promises to sweep in and subject to color additive regulation a substantial number of food ingredients (e.g., chocolate, strawberry syrup) that have a desired color effect but that Congress clearly did not intend to regulate as "color additives." This point is discussed further below.

8/ See, e.g., United States v. American Trucking Ass'ns, Inc., 310 U.S. 534, 542-44 (1940); see generally H. M. Hart, Jr. & A. Sacks, The Legal Process: Basic Problems in the Making and Application of Law 1179-1203, 1410-16 (tent. ed. 1958).

sanctioned substances);[9] and (2) Where a color imparting substance could also be put to a non-coloring use, it wanted to save the agency, when determining whether to regulate the coloring use under section 706, from having to make subjective judgments about whether the primary purpose of a particular dual-function substance was to color or to accomplish some other purpose (hence, it excepted color-imparting substances from the definition only if used "solely" for a non-coloring purpose).[10]

The two limited purposes for which Congress used the term "solely" are satisfied by our application of section 201(t)(1) in this case. First, the objective of comprehensive lists of coloring substances is satisfied because: (a) where nitrites are used in a quantity no larger than is needed for a coloring purpose, they are "color additives" subject to listing under section 706;[11] and (b) the subordinate coloring effect of nitrites in bacon will be reflected in a regulation enacted under section 201(t)(1) excepting it from the "color additive" definition.

Second, the agency will not be in the position of making a subjective judgment about which purpose is primary, because its decision not to regulate nitrites in bacon as a "color additive" is based on the objective existence of a concurrent

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9/ H. Rep. No. 1761, 86th Cong., 2d Sess. 63-64. This objective was particularly important because in the period between the effective date of the FAA (September 6, 1958) and the enactment of the CAA (July 12, 1960) regulation of color additives was inconsistent and not entirely comprehensive. In that period, coal-tar colors were subject to one set of rules and non-coal-tar colors were regulated under a different set of rules established by the FAA. Merging these two systems thus had important practical as well as safety-related purposes.

10/ 106 Cong. Rec. 13312-3 (June 25, 1960).

11/ In the context of nitrites in bacon, it should be recalled that no food processor currently uses nitrites to color but not preserve.

non-coloring effect that is clearly and objectively predominant in terms of the amount of nitrites needed to accomplish it. That is, if nitrites are viewed solely with respect to their preservative function, the amount that is required for that function and that is authorized for use under the statute clearly and objectively predominates over the coloring use. In this respect, it can properly be said that as a practical matter nitrites are used solely for preservation because the desired coloring effect has absolutely no impact on the amount used.

Indeed, if we were to conclude that nitrites in bacon are a color additive on the ground that the processors "desire" the coloring effect, we would be making precisely the kind of subjective determination of purpose Congress intended the agency to avoid. The congressional policy of avoiding such subjective judgments about the purposes and intentions of food processors can most effectively be carried out by disregarding coloring effects that are an unavoidable accompaniment of a predominant food additive effect (here, preservation). In determining which purpose to regard as controlling, FDA need only consider the amount of the substance that may lawfully be used (as an approved food additive, a GRAS substance, or a prior-sanctioned substance) for the non-coloring purpose. Where that amount is larger (and here it is clearly larger) than the amount needed for a coloring effect, FDA can make a straightforward and objective determination that the non-coloring purpose is the sole purpose; any other objectively subordinate purpose (whether desired or not) may be disregarded.

The language of the definition of "color additive" in section 201(t)(1) of the Act expressly leaves it to the agency to "determine ... [whether a substance] is used (or intended to be used) solely for a purpose or purposes other than coloring." The agency plainly has enough discretion to make that determination in a manner that carries out the congressional purposes without also producing absurd consequences.

For these reasons, it is correct to read the exception clause in section 201(t)(1) as permitting the agency to except nitrites in bacon, by regulation, from the "color additive" definition. Congress apparently did not foresee the peculiar circumstance presented by nitrites in bacon--that is, a color-imparting substance being put to a prior-

sanctioned, food additive-type use (preservation) at a level far exceeding that required to accomplish the coloring effect. When a literal reading of a statute will lead to consequences Congress did not intend, it is the duty of the responsible administrative agency to give that statute a reasonable interpretation that comports with the intent of Congress and permits the agency to carry out its responsibilities.12/ That is what we have done here.

The agency has rejected a literal reading of the term "solely" in the past when not to do so would have led to anomalous, and obviously unintended, results. For example, in §70.3(f) of its color additive regulations, 21 CFR 70.3(f), the agency declared that food ingredients such as cherries, green or red peppers, chocolate, and orange juice are not "color additives" when mixed with other foods even though it is clear that they impart color and, as in the case of chocolate, for example, clearly have a desired (though incidental and unavoidable) coloring effect (manufacturers want chocolate candy to be brown). If "solely" were read literally, these substances would be "color additives" subject to pre-market approval under section 706, as would a large number of other food ingredients (e.g., strawberry syrup, egg yolks, etc.) that Congress never intended to regulate as color additives. These substances are analogous to nitrites in bacon in that their coloring effect is an unavoidable incident of a predominant food additive-type use. The regulation excepting these ingredients from the color additive definition was proposed in 1961 (26 FR 679 (January 24, 1961)), and thus reflects the agency's contemporaneous, and heretofore unchallenged, interpretation of the Color Additive Amendments of 1960.13/

12/ Cf. Udall v. Tallman, 380 U.S. 1, 16-17 (1965); and the authorities cited in footnote 8, supra.

13/ In addition to these food ingredients, a substantial number of cosmetic ingredients, such as white talc, which are used primarily for non-coloring purposes but have a desired and unavoidable incidental coloring effect, would become subject to "color additive" regulation under a literal reading of the term "solely."

In support of your literal interpretation of the term "solely," you cite the interpretative statement contained in §70.3(g) of FDA's color additive regulations, 21 CFR 70.3(g).[14] That statement clearly does not, however, reflect an across-the-board literal reading of the term "solely" by FDA. This conclusion is required by the fact that in the immediately preceeding (and simultaneously promulgated) paragraph of its regulation (§70.3(f)) the agency specifically excepted from the "color additive" definition certain color-imparting food ingredients (e.g., chocolate) despite the obvious importance of their coloring effect in terms of "... appearance, value, marketability, or consumer acceptability...." Section 70.3(f) thus makes it clear that §70.3(g) was never intended to preclude the kind of reasonable interpretation of section 201(t)(1) that we have adopted with respect to nitrites in bacon.

In considering how the general language used in §70.3(g) squares with the specific exceptions recognized in §70.3(f) (and with our present application of section 201(t)(1) to nitrites in bacon), the agency has looked into the history of the promulgation of the two provisions and has searched for evidence of the manner in which the agency has applied §70.3(g) in the past. There are no explanatory preambles,[15] and to date we have discovered no other agency documents, that explain the relationship between the two provisions. Moreover, we know of no instance in which §70.3(g) has been the basis for the agency either issuing or declining to issue a regulation excepting a color-imparting substance from the "color additive" definition. Having found nothing in the record to shed light on the original intent underlying §70.3(g), the agency must either regard it as a no-longer

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14/ §70.3(g), 21 CFR 70.3(g), provides:

> (g) For a material otherwise meeting the definition of "color additive" to be exempt from section 706 of the Act, on the basis that it is used (or intended to be used) solely for a purpose or purposes other than coloring, the material must be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. (It is not enough to warrant exemption if conditions are such that the primary purpose of the material is other than to impart color.)

15/ See 26 FR 679 (January 24, 1961) and 28 CFR 6439 (June 22, 1963).

viable historical artifact (which should be amended or revoked) or give it a reading, based on our experience under the CAA, that makes §70.3(g) consistent with §70.3(f). The agency is exploring these options.16/ If it concludes that §70.30(g) as currently written is misleading or serves no useful purpose, the agency will take appropriate steps to amend or revoke it.

We regard our application of the statute in this case (and the resulting conclusion that nitrites in bacon are not "color additives") as consistent with the agency's duty to protect the public health with the authorities given it by the Congress. First, in light of the prior sanction for nitrites in bacon, it is not clear that a literal construction would have any effect at all on the marketing status of nitrites in bacon. Although we have not resolved what is now only a hypothetical legal question, it might well be that regulation of nitrites in bacon as a "color additive," whatever the outcome of that regulation might be, would have no legal effect on the prior-sanctioned, higher-level preservative use of the substance. (If it did, the effect would be, as we have noted, to infer an unstated congressional reversal through the CAA of the legal status Congress had granted nitrites in bacon only two years before.) Second, notwithstanding the prior sanction for nitrites in bacon, FDA and

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16/ One approach to §70.3(g) that makes it consistent with §70.3(f) is to read it as an anti-deception provision that applies only when the possibility exists that deception will result from the use of a coloring material that has other non-coloring effects. The congressional policy against deceptive uses of coloring materials (see 21 U.S.C. §376(b)(6)) favors the retention of any deceptive use of a coloring material in the "color additive" category regardless of whether the coloring effect is clearly subordinate to, or an unavoidable incident of, a predominant non-coloring effect. This approach would be consistent with the exceptions granted in §70.3(f) for substances like chocolate and with the agency's conclusion regarding nitrites in bacon because the use of those substances does not result in deception (e.g., no consumer is deceived when chocolate is colored brown, just as no consumer is deceived when bacon has the characteristic color imparted by nitrites).

USDA remain able under their respective statutes to take the measures they find necessary to protect the public, including, if appropriate, complete removal of added nitrites from the food supply. See 21 U.S.C. §342(a)(1), (2); 21 U.S.C. §601(m).

As you know, FDA and USDA have been working together for several years to deal with the nitrites problem. USDA has taken steps to minimize the amounts of nitrites added to food, consistent with the need to protect against the risk of botulism. FDA is continuing its review of the Newberne study, which, we hope, will provide a fuller understanding of any risk posed by the use of nitrites. The nitrite problem is thus the focus of a comprehensive effort being carried on by the responsible agencies. The agencies have the legal tools they need to deal with nitrites, without embarking upon a construction of the statute that would have the broad and anomalous consequences promised by your approach.

In light of our conclusion that nitrites in bacon are not color additives, it is not necessary to address the argument in your petition concerning the legality of placing nitrites in bacon on the provisional list of color additives.

III. Response to Comments

FDA received twenty-seven comments on your petition. Most of the comments did not deal directly with the factual and legal issues posed by your petition but, rather, expressed individual preferences regarding the result the agency should reach.

In addition, several comments were submitted by or on behalf of the meat industry. These comments made three basic arguments. Their primary argument was that nitrites do not "impart" color to bacon but only "fix" the color and that FDA has taken that position for many years. They also argued that, if nitrites are found to "impart" color, they should nevertheless be excepted from the "color additive" definition because they are used "primarily" or "solely" for a non-coloring purpose (i.e., preservation). Finally, the industry comments argued that a reversal of FDA's "longstanding" position that nitrites in bacon are not "color additives" should be preceded by notice and comment rulemaking.

As noted (and explained in the appendix), we have concluded tentatively that nitrites "impart" color to bacon by reacting with a substance naturally present in the meat to form a third substance that gives the meat a reddish appearance. (Several comments from scientific sources included descriptions of the chemical process by which nitrites have their coloring effect that are consistent with the description in the attached appendix.) The fact that the color given meat by nitrites is similar to the natural color of meat does not warrant the conclusion that the effect of nitrites is merely to "fix," rather than "impart," color. In any event, the issues concerning whether nitrites impart or only fix color will be further addressed and resolved in the forthcoming rulemaking proceeding.

We have agreed with the position taken in some of the industry comments that nitrites in bacon meet the exception clause of section 201(t)(1), but our reasoning, explained above, differs. As noted in footnote 5, supra, we do not accept AMI's assertion that coloring is not an "intended" effect of the use of nitrites in bacon.

IV. Summary

For the reasons set forth in this letter, FDA has concluded tentatively that nitrites "impart" color to bacon, within the meaning of section 201(t)(1), but qualify for the exception from the "color additive" definition that applies to substances "used (or intended to be used) solely for a purpose or purposes other than coloring."

As noted, the agency will, in the near future, initiate rulemaking under section 201(t)(1) of the Act to implement the tentative conclusions set forth in this letter.

Sincerely,

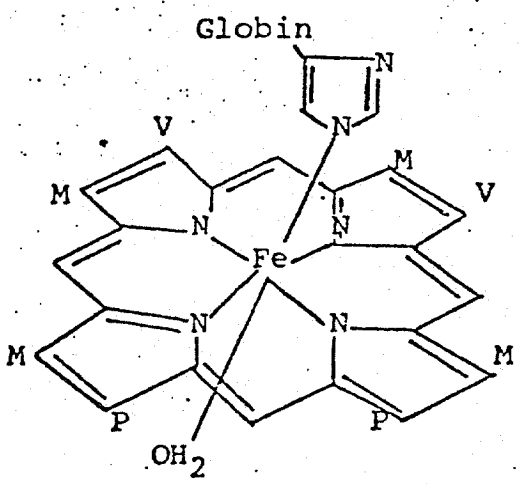
Donald Kennedy
Commissioner of Food and Drugs

Attachment

Appendix: Coloring Effects of Nitrites Used In The Curing of Meat.

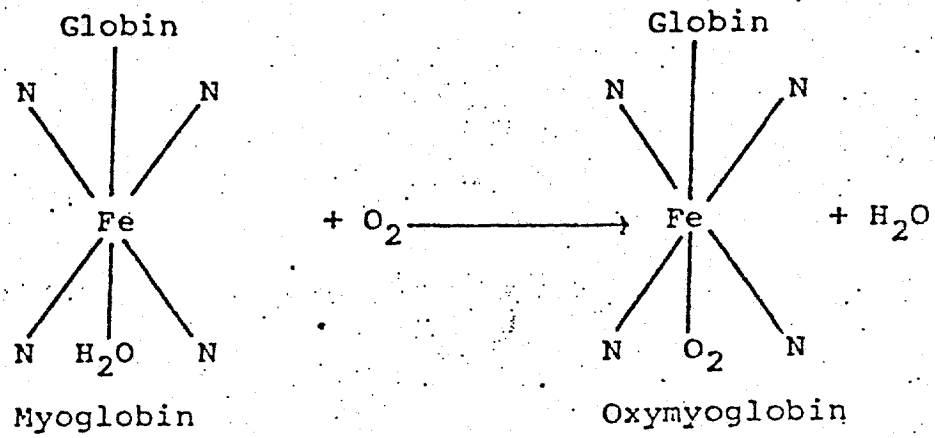
This appendix discusses the chemical process by which nitrites impart color to red meat, including bacon.

The primary coloring substance in meat is myoglobin. This is the chemical molecule present in muscle tissue that is responsible for the transfer of carbon dioxide and oxygen to and from the blood. Myoglobin can be depicted as having the following chemical structure:

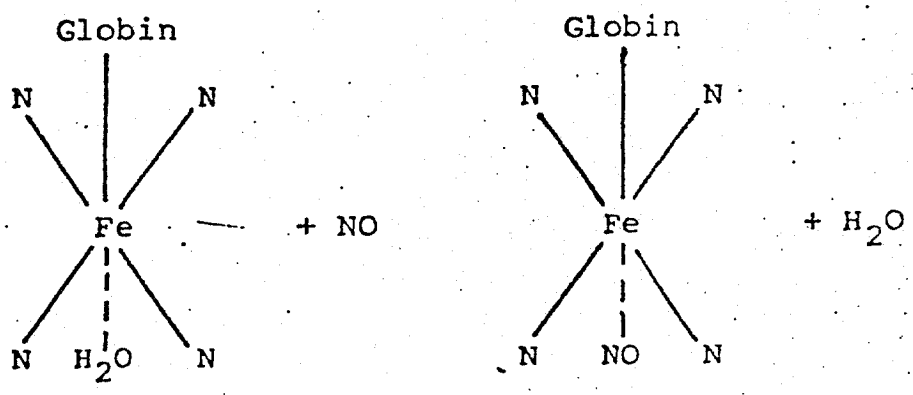


Schematic representation of the heme complex of myoglobin.

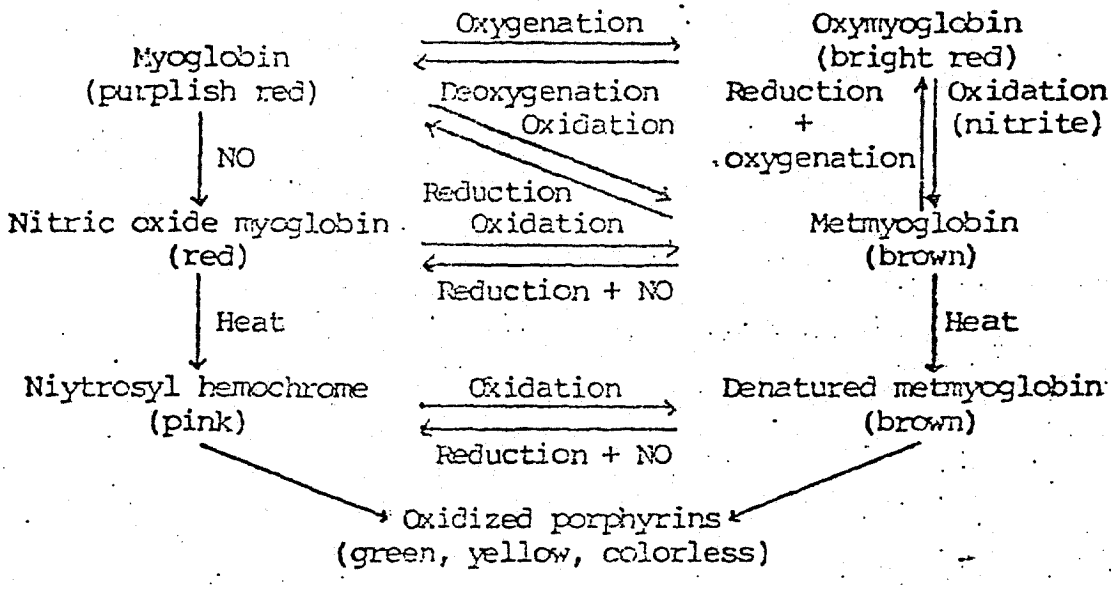
Myoglobin imparts a purplish red color to meat. The intensity of the color is dependent upon the concentration of myoglobin. The bright red color of freshly cut meat, such as a beef steak, is due to the presence of oxygenated myoglobin or oxymyoglobin. In this case, oxygen from the atmosphere has replaced the water bound to the home complex in myoglobin, as follows:



In the curing of meats with nitrites, however, the water bound to the myoglobin is displaced by nitric oxide to form nitric oxide myoglobin, as follows:



The nitric oxide myoglobin provides a red color to the meat. The difference between fresh meat and cured meat is that upon heating oxymyoglobin yields denatured metmyoglobin, which is brown, while nitric oxide myoglobin yields nitrosyl hemochrome, which is pink. These various pathways for the reactions that can occur with myoglobin can be summarized with the following schematic:



The above information and diagrams have been obtained primarily from The Science of Meat and Meat Products, edited by Price and Schweigert (Freeman & Co., 1971). These are essentially the same reaction pathways diagrammed in Figure 2 of the short book entitled Meat Curing Principles and Modern Practice by Robert G. Rust and Dennis G. Olson (1973), which was attached to Dr. Jacobson's affidavit and submitted as part of the citizen petition filed by Mr. William Schultz concerning the color additive status of nitrites in bacon (FDA Docket No. 79P-0077).