HEALTH CONCERNS AND REGULATIONS CONCERNING COLOR ADDITIVES AND THE CONSUMER

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HEALTH CONCERNS AND REGULATIONS

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INTRODUCTION

One of the main objectives of the food industry is to provide a continuing supply of safe, pure food for the public. In order to achieve this goal, the food industry must be concerned about the possible deterioration of foods, their contamination with potentially hazardous chemicals, and the safety of color additives or other materials used in food processing. Color additives are so prevalent in our environment that we are not always aware of just how much we depend on them. Color is important to man as a means of identification and as a method of judging quality. Consequently, it is no wonder that for centuries color has played such an important role in food production.

History is replete with accounts of widespread application of color additives. Painting in Egyptian tombs dating as far back as 1500 B.C. depicit the making of colored candy. The coloring of spices and condiments is known to have been practiced at least 500 years ago (Marmion, 1979).

Until the middle of the nineteenth century, the colorants used in foods were materials easily obtainable from natural sources, that is, animals, vegetables and

minerals. In 1856, the first synthetic organic dyestuff, mauve, was discovered by Sir William Henry Perkin. Soon a host of new and different colorants were developed.

The use of some of these colorants in foods began in Europe. French wines were colored with fuchsine, a triphenylmethane dye, as early as 1860. The use of food colors in the United States was first legalized by an Act of Congress in 1886, authorizing the addition of coloring matter to butter. The second authorization came some 10 years later in 1896 when Congress recognized coloring matter as a legitimate constituent of cheese. By 1900 Americans were eating a wide variety of artificially colored products including ketchup, jellies, butter, cheese, ice cream, candy, sausage, noodles and wine.

The extensive use of color additives was soon recognized as a threat to the nation's health. Of particular concern was the fact that poisonous substances such as, chrome and martuis yellows (lead sulfate based pigments) and quicksilver vermillion (a mercury based pigment) were sometimes added to foods. These heavy metal dyes were frequently used to hide poor quality, to add weight or bulk to certain items. Another concern was the fact that little or no control was exercised over the purity of the colorants used in foods and dyes found unsatisfactory for textiles, but sometimes deliberately channeled into food products. Public awareness that such materials as arsenic acid and mercury were employed in the

manufacture of various colorants soon created a new fear of coal-tar dyes. This fear lingers even today. Because of increasing public concern some measures were taken by food manufacturers to police their own industry. An example was the list published in 1899 by the National Confectioner Association for coloring matters that they considered unfit for coloring food. However, the effect of such actions by industry was marginal and it was soon obvious that government control was necessary.

The first effective step taken by the government to check such practices was under the Appropriations Act of 1900 for the Department of Agriculture. The Bureau of Chemistry was given funds to investigate the relationship of coloring matters to health and to establish principles that should be followed to govern their use. Results came quickly with the issuance of a series of Food Inspection Decisions (FID) by the Secretary of Agriculture.

About the same time a thorough study was undertaken by the Department of Agriculture to determine which dyes, if any, were safe for use in foods and what restrictions should be placed on their use. This task eventually included a study of the chemistry and physiology of the then nearly 700 extant coal-tar dyes as well as the laws of various countries and states regarding their use in food products.

On June 30, 1906, Congress passed the Pure Food and Drug Act which became effective on June 4, 1907. "The

Pure Food and Drug Act made the adulteration and misbranding of foods and drugs entering interstate commerce illegal" (Olsen, 1911). It stated that substances could be added to food only if they were not likely to render the food injurious to health.

The administration of the act was given to the U. S. Department of Agriculture with no fines or penalties included. The effectiveness of the act was lessened by limited personnel, lack of enforcement powers and poor analytical methods.

In 1931 the Food and Drug Administration (FDA) was created to administer the food and drug law. Due to the same weaknesses and limitations as the Pure Food and Drug Act, a new bill was introduced in 1933. After many hearings and revisions, Congress passed the Food, Drug and Cosmetic (FD&C) Act in 1938. This FD&C Act was developed to protect consumers' health by prohibiting the use of certain substances in foods and by requiring that the presence of all ingredients be stated on the label.

The 1938 Act provided requirements on informative labeling, strengthened the safeguards toward public health and preventive deception and included cosmetics and therapeutic devices that formerly escaped regulations. The Act gave the FDA power to seize illegal products and to fine and imprison violators of these laws. It also provided for a list of all food additives that were generally recognized as safe (GRAS).

Prior to 1958, a reputable food manufacturer could develop and market a new preservative or food flavoring substance or some color additive for use in food without an objective evaluation by a competent group outside the company. The food manufacturers would determine whether the technical or physical effect of the additive would, in fact, produce a marketable product that would have strong appeal to the average consumer. A company's staff or consulting scientists would determine the safety of the new additive. With the increasing number of food additives on the market, it became evident to Congress that a formal controlled procedure of pretesting was essential to insure the safety of the consumer and to permit the consumer to take advantage of modern food technology.

The Food Additives Amendment, enacted in 1958, was to protect the health of consumers by requiring proof of safety before any additive was added to food and to advance food technology by permitting the use of food additives that are safe at the levels of intended use. The Delaney Clause, a rider attached to this amendment, prohibits the addition of carcinogenic additives to foods (Fischbach, 1968).

The Color Additives Amendments of 1960 was designed to provide for the approval of color additives that must be certified or color additives that are exempt from certification. The FDA is empowered to list color

additives for specific uses and to set quantity limitations" (Marmion, 1979). "The Delaney Cancer Clause is also included in the Color Additives Amendments and states that no color additive may be approved for food use in any amount if it is found to induce cancer when used by man or animal" (Fischbach, 1968). The Delaney Clause further provides that whenever a question arises as to whether a color additive may induce cancer, an advisory committee will be established to serve as a fact-finding body.

Color additives now are regulated under the Color Additives Amendments of 1960. They include authorization for establishment of conditions and tolerances for safe use. For the first time all coloring agents were included; dyes, pigments or any coloring substance regardless of how derived. Among the national coloring agents, only one form of carbon black (channel or inpingment process) has been accepted because of the content of polynuclear aromatic hydrocarbons in some forms which have been found carcinogenic for many species (Sjostrom & Kensler, 1969).

Almost all food, from raw agricultural commodities to finished products, has an associated color that is acceptable to the consumer, based on social, geographic, ethnic and historical background. For instance, the U. S. Department of Agriculture grade standards for fresh fruit and vegetables are based on color, shape, size, maturity,

and degree of defects. Margarine did not become a popular product until its flavor was perfected and manufacturers were permitted to add color. Certain foods have been artificially colored for years, and we have come to expect them to have a characteristic color intensity and hue (Gilchrist, 1981).

Optimium color is extremely important in consumer acceptance. It would be useless to try to persuade the consumer to buy gray raspberries because they have optimium flavor, or tasteless raspberries because of optimium color. Color is one of the most important independent variables influencing acceptance. While color is straightforward from the standpoint of chemistry and measurement, it is complex from the standpoint of psychology and acceptance.

As an index of the need for added color, it is estimated that more than 2 million pounds of synthetic certified colors are used annually by the food, drug and beverage industries. In addition to these colors, there is still a larger volume of natural origin colors or colors derived from natural products such as annatto, carmine, caramel, carotene, chlorophyllin, tumeric and xanthophyll.

The problem addressed by this study is that consumers are not aware of the wide use of color additives in our food supply. Because we can not test the color additives for all affects on all people, the consumer should be

concerned that information is available on what color additives are in what products and how they might affect different consumers.

The purpose of this project is to report on an investigative review of the reasons for the use of color additives, at the laws and regulations governing the use of color additives in food production, and how the use of color additives is a concern for all consumers.

REVIEW OF LITERATURE

Reasons for Use

With all the problems associated with the manufacture and sale of color additives, we might ask, "Why Bother?" The answer is not simple and is not the same in all situations.

Color is added to food either because the color of foodstuff varies greatly with the season of the year or the geographic origin of the product. It is also added because it has no natural color of its own, or because its natural color is lost or drastically altered as a result of processing or storage. Whatever the reason in any particular case, the overall objective of coloring food is to make it recognizable and appealing to the consumer so that the product will be purchased.

The regional and seasonal problems with food production are seen in the citrus fruit and dairy industries. Consider the growing of oranges; in many parts of the United States the soil and weather conditions are such that chlorophyll, the green photosynthetic coloring matter of plants, continuously forms in the fruit as well as in the leaves of the trees. This results in

mature oranges that are substantially greener than the same variety of oranges produced in regions of the country with different growing conditions. Florida Valencia oranges, for example, mature in the latter part of March when the weather is favorable to the development of chlorophyll, which is produced in such quantities that the fruit peel eventually turns pale and green. In fact, most varieties of Florida oranges tend to be green, suggesting immaturity, even though they contain the proper ratio of solids to acid for fully nutritious, mature fruit (Marmion, 1979).

The necessity of coloring these oranges to make them comparable in appearance and thus as commercially acceptable as naturally orange colored fruit from other areas of the country was recognized years ago and began on a commerical scale about 1934. Today the peels of those oranges not intended for processing continue to be dyed where necessary. The percentage of the total crop colored varies from year to year and depends largely on the weather.

The problems of the dairy farmers are no less complicated. Approximately 90% of the yellow color in milk is due to the presence of B-carotene, a fat-soluble carotenoid extracted from feed by cows. Summer milk is more yellow than winter milk. This is largely due to seasonal feeding practices in which cows grazing on lush green pastures in the spring and summer consume much

higher levels of carotenoid than do cows that are fed hay and grain in the fall and winter. The problem is further complicated since various breeds of cows and even individual animals differ in the efficiency in which they extract B-carotene from feed and in the degree to which they convert it into colorless vitamin A. The differences in the color of milk are more obvious in products made from milk fat, since the yellow color is concentrated. Therefore unless standardized through the addition of color, products like butter and cheese, would show a wide variation in shade and appear unsatisfactory to consumers.

In addition to standardizing the color of butter and certain yellow cheeses by the addition of yellow colorants, it is frequently necessary to use various amounts of blue or green colorants when making Gorgonzola, Nuworld, Provolone, Blue and various other cheeses in order to neutralize the yellow of the curd used to prepare them. Other products whose natural color varies enough to make standardization of their color desirable include the shells of certain kinds of nuts and the skins of red and sweet potatoes and ripe olives.

Often the process used to prepare foods leads to the formation of a color in the product, the depth of which depends largely on the time, temperature, air exposure and other parameters experienced during processing. Here again it is necessary to supplement the color of the product to insure its uniformity from batch to batch.

Items that fall into this category include certain beers, blended whiskies, brown sugars, table syrups, toasted cereals and baked goods.

The storage of foods can also be a problem since natural pigments often deteriorate with time due to exposure to light, heat, air and moisture or because of interactions of the components of the product with each other or with the packaging material. The color of maraschino cherries, for example, fares so poorly with storage that they are routinely artificially colored (Marmion, 1979).

However, the most common use of color additives is in products containing little or no color of their own. These include many liquid and powdered beverages, gelatin desserts, candies, ice creams, sherberts, icings, jams, jellies, and snack foods. Without the addition of color to some of these gelatin desserts and soft drinks, all flavors of the particular product would be colorless, unidentifiable and probably unappealing to the consumer.

Laws & Regulations Governing the Use of Color Additives

The first coloring agents added to foods were the natural types, annatto extract, saffron, paprika and caramel. These color additives were not satisfactory in food manufacturing because of their heat and light

instability, as well as their lack of uniformity. As synthetic dyes and pigments became available, they almost completely replaced the naturally derived products.

Color additives may be divided into three categories: synthetic organic compounds (certified colors or coal-tar dyes), naturally derived colorings (uncertified color additives), and mineral or synthetic inorganic colors (pigments and lakes). Of these the synthetic organic compounds are the most extensively used. A few natural colors are routinely used in a limited number of products and synthetic inorganic compounds are rarely used in food products.

Out of the many coal-tar dyes or certified colors known, only a few are permitted by law for use in foods. These colors make up the primary food colors, and when blended or mixed produce the secondary colors. All of the permitted dyes possess common names and have numbers assigned to them. All are subject to FDA certification for purity. After passage of the Food, Drug and Cosmetic (FD&C) Act of 1938, a new system for designation of these dyes was adopted. The new system gave the use for which the color is permitted, the predominant shade of the color, and a number to distinguish the color from others of the same shade. The term Food, Drug and Cosmetics (FD&C) colors are certified for use in foods, drugs and cosmetics. The Drug and Cosmetics (D&C) colors are dyes and pigments considered safe in drugs and cosmetics when

in contact with mucous membranes or when ingested. The Extant D&C colors are colorants that, because of their oral toxicity, were not certifiable for use in products intended for ingestion, but were considered safe for use in products externally applied. This system clearly differentiates between a textile grade colorant and a certified colorant with the same chemical structure, but having a different level of purity. It also prevents one manufacturer from gaining an advantage over competitors since trade names are not used to identify colors.

The Color Additives Amendments required the listing of all food colors. This listing was divided into two groups; those permanently listed and those provisionally listed. Listed or permanent additives are colors that have been sufficiently evaluated to convince the FDA of their safety for the application intended. Provisionally listed colorants are dyes and pigments that are not considered unsafe but that have not undergone all the tests required by the amendment to establish their eligibility for permanent listing. Currently, these colors can only be used in those applications in which they were used prior to enactment of the 1960 amendments. Their status is reviewed about once each year. If sufficient reason exists and if the manufacturers or consumers of these colors request it, their provisional listing status is extended pending completion of the required scientific investigations.

To develop and evaluate a colorant and obtain permanent listing status for the color may take from five to seven years, depending on its intended use. In the case of FD&C colors, a complete evaluation usually includes long-term internal and external toxicological testing, chemical and shelf-stability studies, and trial runs in typical commercial products. Toxicological testing might include a two year feeding study on dogs and rats, repeated dermal application tests on rabbits and mice, and two generation reproduction studies with rats. In each case the test animals are compared with control groups with respect to survival, appearance, behavior, appetite, elimination, organ weights and ratios, tissue structure, skeletal structure, and other variables, depending on the test involved (Aurand, 1987). Where reproduction studies are concerned, the offspring are similarly evaluated. Chemical and shelf-stability studies include the determination of the effect of light, heat, time, acids, alkali, and moisture. Application studies involve determining the stability and effectiveness of the colorant in the kinds of products and types of containers in which it is intended for use. This data, as well as information relating to the manufacture, analysis, control and packaging of the color, and the proposed specifications and anticipated levels of use of the color are incorporated into a petition which is sent to the FDA for their review. Public notice of the filing of the

petition and the FDA decision regarding the petition are published in the Federal Register.

A further distinction between color additives is made relative to whether there is a requirement for FDA certification. Certification of colors relates only to their purity and not to their safety.

The FDA has the tremendous responsibility of protecting every man, woman and child in the country from death or injury by the adulteration or misbranding of foods and drugs (Welch & Marti-Ibanez, 1956). The 1938 FD&C Act is a public law of profound social and economic importance to our country. The Act governs our most essential food and drug industries and regulates our most essential food and drug products. It does so for the purpose of protecting the public health by prohibiting an injurious processing or labeling of its products.

Chemical substances may evoke toxicological effects if the absorbed dose is sufficiently high and the time of exposure is sufficiently long. The possibility of causing long-term toxic effects by the use of color additives has alerted toxicologists to require extensive and strict animal testing prior to utilization of these substances in food. This is done in order to protect the health of the consumer (Vettorazzi, 1981).

At the time of passage of the 1938 FD&C Act, seventeen approved synthetic colors were certifiable for use. Two were added later. This list was compiled from

previous history of safe use in food products and limited additional toxicological and pharmacological data. "It was not until 1950 that a real issue was raised as to the inadequacy of the law" (Zuckerman, 1962). This happened when a candy company made a quantity of Halloween candy adding enough FD&C Orange No.1 to match the color of pumpkins. A number of children who ate this candy had severe gastrointestinal upsets. "This incident pointed up the absurdity of the 1938 Act which the FDA practically was required to certify that this color was edible, and was not authorized to establish any upper limit for its concentration in foods" (Zuckerman, 1962). At this time, the FDA recognized the lack of adequate toxicological information on most of the certifiable colors as well as their inability to regulate the amount to be used. The FDA then initiated long-term animal tests to gain more adequate information. In 1955, a committee was appointed by the National Research Council to make recommendations on the FDA certified coal-tar color program. The committee recognized that only one of the FD&C colors had been adequately tested and proven reasonably safe for use by modern toxicological standards under all probable conditions of use. This was tartrazine (FD&C Yellow No. 5). It was estimated by this committee that if the certified color testing programs were to be continued at the rate then in operation in the FDA's laboratories, it would probably take 25 years to accumulate the necessary

experimental information. The colors used in food, however, had priority. Since that time, eight of the nineteen certifiable dyes have been removed from the list for various reasons. The dye FD&C Red No. 1 was found to be a hepatotoxic agent, and FD&C Yellows Nos. 3 and 4 were reported to contain small amounts of beta naphthylamine, a known bladder carcinogen. They were reported to breakdown in acid media yielding beta naphthylamine (Harrow & Jones, 1954). At present, of the remaining eleven certifiable food colors, six year feeding experiments have indicated the safety of nine. Studies are in progress on the other two and have not indicated any hazard (Sjostrom & Kensler, 1969).

There is increasing recognition that food safety laws and policies need to be revised. Congressional debate on proposed amendments to the FD&C Act has generated several different perspectives on how the food safety laws should be changed. Before a consensus can be reached, scientists, regulators, the food industry and consumers will have to review such complex and controversial issues as the level of acceptable risk, the value of risk-benefit analysis, the proper role of independent scientific review, and the reliability of quantitative risk assessment (Kessler, 1984).

In August 1985, the Health Research Group filed a petition asking for a ban on ten provisionally listed color additives. The petition was denied so that a

scientific panel could review evaluations of their safety. The panel had to determine if there was sufficient scientific data to conduct a proper risk assessment of the color additives. In view of the fact that no short-term tests exist that could help resolve the safety questions, the FDA issued a five year extension to the provisional color listing to permit chronic testing (Smith, 1985A). Originally, there were more than 200 color additives on the 1960 provisional list. Only 11 remain and only three of these, FD&C Red No. 3, FD&C Yellow No. 5 and FD&C Yellow No. 6, are used in foods (Sun, 1985B).

After 25 years of deliberation by the FDA, the debate continues about the interpretation and enforcement of the Delaney Clause. It is questioned whether Delaney is an outmoded law because it does not take relative risk into account. If the dyes pose only a negligible risk, it makes no sense to brand them as illegal and disrupt the marketing of a considerable number of products. Using the concept of negligible risk to interpret the Delaney Clause will be given serious consideration in banning cancer causing additives (Lehman, 1969). The House Committee was divided on whether Delaney should be modified. However, they concluded unanimously that the Office of Management and Budget had improperly interferred with the FDA's decision making process and that the FDA had failed to enforce Delaney as it stands now. The House Committee felt that the FDA should take the necessary steps to

enforce the Delaney Clause to make sure that the public would not be exposed to carcinogenic color additives (Sun, 1985A). The food industry seems to be fighting a loosing battle to save what they consider to be an important group of colors derived from petroleum. These pigments, which include the last of the yellows and a red which is considered irreplaceable, are all suspected carcinogens. The food industry claims their studies show that the risk of cancer from any of these colors is virtually nonexistent. However, the FDA says they are convinced that many of the colors in question are carcinogenic and should be removed from the market. The FDA also agrue that children, who are major targets of food dyes, consume up to three pounds of food dye by the age of 12 (Rhein, 1985B).

Robert Pulver, a board member of H. Kohnstamm of New York City, a major colorant manufacturer, states: "that if all the colorants were taken off the market, we would be hurt, but the food industry would be hurt more." The National Food Processors Association says as much as $25 billion worth of food products have FD&C Red No. 3, D&C Red Nos. 8, 9, 19 and 37, and D&C Orange No. 17 added to them. FDA Commissioner Frank E. Young has publicly hinted that he will recommend a ban on all of the dyes except FD&C Red No. 3. This particular red dye is still under study for possible threshold levels of safety. This dye is important to food processors because it is the only red

that does not bleed out from the cherries into the syrup in fruit cocktail (Rhein, 1985A).

In an FDA Consumer Update (May, 1986B), a U. S. District Court ruled in favor of the FDA in a lawsuit by Public Health Citizens Health Research Group (PHCHRG) that sought to ban nine provisionally listed color additives. PHCHRG claimed that the FDA had sufficient time to analyze the safety of the additives and that the continued provisional listing violated the Color Additives Amendments. The court rejected both contentions and ruled that the latest extension of the provisional listing was within the FDA's authority. The FDA has appointed an expert panel of government scientists to evaluate additional data and assess the potential risk of the nine colors. Upon evaluation of the panel's report, the FDA will announce further action.

The FDA has decided to permanently approve five color additives: D&C Orange No. 17, D&C Red Nos. 8, 9 and 19, and FD&C Yellow No. 6. The decision to permanently list the five colorants was based on conservative risk assessment and analysis by a scientific review panel composed of experts from five government agencies, the FDA, the U.S. Center for Disease Control, the National Heart, Lung and Blood Institute, the National Cancer Institute and the National Institute for Occupational Safety and Health. The permanent listing of the five colorants was published in the Federal Register (Smith, 1986C).

Some FDA actions could affect the incidence of cancer in the United States. First, the agency has sought to circumvent the Delaney Clause. Second, it has relied on a voluntary program for labeling.

The FDA did consistently interpret the clause to prohibit the addition of carcinogens in any amount, but in 1982, they reversed its policy to permit approval of color additives containing detectable amounts of carcinogenic contaminants if they were not added intentionally. However, the concept of unintended additives has little relevance when the concern is health effects. Exposure, and the fact that industry did not choose to add a contaminant, provided little consolation to the exposed members of the public.

Labeling, which involves the dissemination of information about a product's content, is one of the least burdensome forms of regulations. However, the FDA proposed a voluntary labeling program despite widely voiced concerns that a mandatory program was necessary to enable consumers to control their intake of additives.

In light of these issues, the FDA has failed to fully implement the mandate of labeling in order to protect the public's health. With an issue like this, it is in the best interest of the American public to not rely on voluntary labeling (Wirth, 1984).

The most important factor for the acceptance of a substance as a food additive is the establishment of its

safety in use. This implies that an adequate toxicological evaluation has to be made. While it is impossible to establish absolute proof of the non-toxicity of a specified use of an additive for all human beings under all conditions, critically designed animal tests of the physiological, pharmacological and biochemical behavior of the proposed color additive can promote a reasonable basis for evaluating the safety of its use at a specified level of intake. Any decision to use an intentional additive must be based on the considered judgement of properly qualified scientists that the intake of the additive will be substantially below any level which could be harmful to consumers. The decision as to a safe level should be based on knowledge of the maximum dietary level that does not produce an unfavorable response in test animals, and of the estimated potential intake of the additive.

In applying these concepts to the use of food colorants, it has been observed that, while there are cases in which the use of these additives is justified, the best method for regulation is the establishment of a list of permitted colorants which have been adequately tested by animal experimentation. There is agreement that colorants produce cancer on oral administration and need to be eliminated from these lists. There are, however, some colorants which do not produce cancer in animal feeding tests but which, on injection, produce a

significant number of sarcomas at the site of injection. In some countries, induction of such sarcomas is considered sufficient to indicate that a substance can not be regarded as safe for man, and it is considered prudent to reject the substance for use in food until more proof of safety is available. In any case, the use of food colorants which have not been sufficiently tested is undesirable--particularly those which are known to be carcinogenic, such as auramine O, and tetramethyl diamino diphenyl cetonimine hydrocholoride (Vettorazzi, 1981).

Since the components present in food colorants may be carcinogenic, it is particularly important that rigid chemical specifications be established and maintained for all food colorants. In all cases, the potential risks should be considered in relation to the advantages of their use.

It should be recognized that the most uncertain aspect in safety evaluations is the relevance of animal data to man. This uncertainity originates not only from the problem of differences of species, but also, and principally, from the very nature of the type of safety index that one wishes to derive from the maximum daily dose of a chemical fed continually to an appropriate animal species without ill-effects.

With regard to experimental evidence of carcinogenicity in experimental animals, many national and international agencies conform to the concept of maximum

safety when dealing with food colorants. Consequently, the value of experimental results in animals in order to predict a similar effect in man, has been, for the most part, accepted as valid. It should be recognized that no adequate criteria are presently available to interpret experimental data on carcinogenicity directly in terms of potential to humans (Vettorazzi, 1981).

Apart from the national agencies, there are three international groups that are actively engaged in the evaluation process of the toxicity of food colorants at the present time. The first is the Joint Food and Agriculture Organizations of the United Nations and the World Health Organization (FAO/WHO) Expert Committee on Food Additives which carry out toxicological assessments on food additives, including food colorants, since 1956. This committee formulates toxicological decisions and issues recommendations in this regard to all member countries of FAO/WHO. The second group is the International Agency for Research on Cancer (IARC) Working Group on the Evaluation of the Carcinogenic Risk of Chemicals to Man, which began its activities in 1971. This group aims at assembling, documenting and evaluating scientific data on the carcinogenic potential of food colorants. The third group is the Scientific Committee for Food of the Commission of the European Communities. This committee was established in 1974 to give advice on any problems relating to the protection of the health and

safety of persons arising from the consumption of food. They are particularly concerned with the composition of food and color additives, other processing aids, and the presence of contaminants. The opinions of this committee are submitted to the Commission of the Europeon Communities and, as a rule, are published (Vettorazzi, 1981).

Consumer Concerns Over Use of Color Additives

The ability of color additives to produce symptoms is a controversial subject, not whether such additives can produce adverse reactions, but which ones produce what adverse reactions and how frequently. The reaction to food coloring is based on controlled studies documenting behavioral disorders associated with food coloring.

Feingold contends that as many as 50 percent or more of the children labeled as hyperactive could be treated successfully by eliminating from their diet synthetic colors, flavors, and certain fruits and vegetables containing natural salicylates. His hypothesis came from clinical and parental observations. These were not controlled experiments but were convincing enough to prompt several controlled trials (Weiss, 1980).

The initial study supporting Feingold's suggestion involved 22 children whose parents felt that the

children's behavior improved on the Feingold diet. The diet avoids such foods as almonds, apples, apricots, berries, cherries, currants, grapes, raisins, nectarines, oranges, peaches, plums, prunes, tomatoes, cucumbers and products made from these foods which are felt to be salicylate containing foods. In addition artificial colors, butylated hydrorytoluene and butylated hydroxyanisal, are avoided. In the study, the children were maintained on the above diet and were then challenged intermittently with a blend of seven artificial colors which included Yellow 5, Yellow 6, Red 40, Red 3, Blue 1, Blue 2, and Green 3. The parent's observations provided the criteria of the response. Their conclusions were that one child responded mildly to the repeated challenges and one responded dramatically. Data from this study appears to suggest that food colors could induce behavior changes in children, but the role of food salicylates, acetylsalicytic acid, or food preservatives have not been determined (Condemi, 1981).

Another study, using larger amounts of color blend, was able to induce adverse reactions in 17 of 20 children. The amounts used were amounts that could easily be ingested in a normal diet. Cognitive performance was measured using different doses and a placebo. All of these children had responded to pharmacological management of their behavior, but had not been on the Feingold diet prior to the study. The data suggested a dose response

curve with children reacting at different levels, but a peak was reached above which no further increase in reaction could be detected (Crook, 1979).

> Swanson and Kinsbourne (1980) in their study state: We increased the dose of color to 100 mg from the 13 mg amount recommended by the Nutrition Foundation and used in most tests of the Feingold hypothesis. With our revised procedures, we documented a relationship between ingestion of this larger amount of artificial color by our patients and a critical symptom of hyperactivity by impairment of attention and concentration as reflected by performance on a laboratory learning test. While this does not provide any evidence that the Feingold diet is an effective treatment, it does call into question the negative findings of previous challenge studies which had been used to completely dismiss the Feingold hypothesis (p. 1485).

The Swanson study used an unreasonably large dose of food coloring mixture and did not satisfactorily demonstrate an effect on test performance that could be confidently distinguished from practice and fatigue. Therefore, their results must be viewed with caution (Wender, 1979).

Another study on food colors and hyperactivity was done with nine hyperactive male subjects. They were selected on the basis of showing a favorable response to

the Feingold diet in an earlier study and were maintained on this strict elimination diet for 11 weeks. During the study they were given multiple trials of placebo and artifical color challenge material. Parental and teacher ratings, classroom behavior observations and neurophychological test scores obtained during baseline, placebo and challenge conditions, in general, were not found to be adversely affected by the artificial color challenge materials (Harley, Matthews, & Eichman, 1978).

In all of these studies, the children were on the Feingold diet, and were challenged with blends of the food colors. At the present time, one can not determine whether one dye or all dyes can produce the change of behavior or whether the food colors can produce reactions in adults. In addition, there is no information concerning the role of salicylates or preservatives in inducing behavior changes.

It appears that food colors can cause behavior changes. The types of change will have to be better defined and their extent determined; whether they occur in adults must also be determined. It is obvious that these reactions are not immunologic and therefore induced reaction requires larger amounts of the materials than allergists usually use in challenges. It also appears that there is a critical threshold below which patients have no reaction. It is, therefore, important to determine uniform challenge doses and to remain within the

amounts ingested by the patient.

A study done by Giri, Talukder, and Sharma (1986) on metanil yellow and nitrite states:

> In vivo sister chromated exchanges (SCEs) induced by metanil yellow (a dye containing secondary amino group), sodium nitrite and dye in combination with nitrite following treatment with acute doses were studied on mice. The incidence of SCEs was significantly high in both dye and nitrite treated series.
>
> The N-nitroso derivatives of secondary amines are known to be highly carcinogenic and are produced in the human stomach by acid catalysed reaction between nitrites present in food. Both nitrite and nitrate may be synthesized in the body from nitrogenous components of the diet and human saliva also contains a significant amount of nitrite. Several vegetables also have high concentrations of nitrates.
>
> Interaction between certain dyes and nitrite in the laboratory has shown the presence of nitrosamines. Apparently, the use of dyes having nitrosable groups may lead to the production of nitrosamines in the nitrite or nitrate containing food or in the stomach itself. Metanil yellow is yet often used to color sweets and soft drinks. In the present investigation, the activity of the dye alone, and in combination with nitrite have been observed on the

> bone marrow chromosomes of mice, using SCEs as the parameters for identifying alterations induced (p. 303).

The overall data indicates an additive effect when dye is given in combination with nitrite. So the investigation shows a possible carcinogenic risk to human beings exposed to high amounts of dye and nitrite through various sources.

The use of synthetic dyes in food and beverages has attracted increasing attention after it was reported that a variety of azo dyes can provoke chronic urticaria, angioneurotic oedema and asthmatic attacks in predisposed patients. Improvement and disappearance of symptoms have been described, when the azo compounds were withdrawn from the diet.

Annatto extract, a commonly used food color in edible fats and butter, has been tested in patients. Among the 61 consecutive patients suffering from chronic urticaria and/or angioneurotic oedema, 56 patients were orally provoked by annatto extract during the elimination diet. Challenge was performed with a dose equivalent to the amount used in 25 grams of butter. Twenty-six percent of the patients reacted to this color four hours after intake. Similar challenges with synthetic dyes showed the following results: Tartrazine 11%, Sunset Yellow 17%, Food Red 17 16%, Amaranth 9%, Ponceau 4R 15%, Erythrosine 12% and Brillant Blue 14%. This study indicates that

natural food colors, which are seldom investigated with respect to potential allergic properties, may induce hypersensitivity reactions as frequent as synthetic dyes (Leonard, 1978).

Adverse reactions to food colorings in pediatric medications can complicate treatment. A four year old girl with asthma and documented allergies to trees, danders, dust and molds reacted to ampicillin, erythromycin and Keflex with wheezing, urticaria and fever. When she developed similar signs after eating a red velvet cake, an investigation was undertaken to determine whether the red dye in the antibiotics had been responsible for her reaction. This was indeed the case with erythromycin and Keflex, for she was able to tolerate both as colorless tablets, but not as colored liquids. She subsequently had wheezing provoked by red hot dogs, pink ice cream and red Kool-Aid.

What is remarkable, is that in spite of the growing awareness of reactions to additives in food and drugs, there is still no available index to dyes in medication. The FDA has a list of approved food dyes but has no comprehensive index to dyes in particular products (Lewis, 1979).

In 1983 Dr. Heather Linklater underwent extensive additive testing by Dr. Marshall Mandell, an allergist. Mandell found that the yellow food dye, tartrazine, brought severe loss of coordination and extreme sleepiness

to Dr. Linklater after ingestion (Corelli, 1987). Tartrazine is used by McDonald's restaurants in their vanilla milkshakes.

Misconceptions about the word safe prevents people from looking at color additives realistically. The problem is a lack of public understanding of the nature of risk and the nature of safety. You can never prove that something is safe; you can only prove that under the conditions in which you tested it, it did not produce any adverse effect.

SUMMARY AND CONCLUSIONS

Color is a very important independent variable in the manufacturing and processing of foods in our environment. The use of color in food production helps correct for natural variations in color or for changes during processing and storage. Color makes food more visually appealing and helps emphasize or identify flavors normally associated with various foods. It also assures greater uniformity in appearance and it helps preserve the identity or character by which foods are recognized. Without color, foods would be unidentifiable and unappealing to consumers.

Consumers, in general, are not aware of the wide use of color additives. Due to this lack of awareness, there is an increased need that the laws and regulations be adequate and thorough enough to assure the safety of consumers. The laws should also be strictly enforced in order that no harmful substances, regardless of amount of risk, be allowed to enter our food supply. Following an extensive review of related literature, I feel that safety of color additives should be a major concern to the majority of consumers. Although absolute safety is unavailable, I think we do need a high but realistic

degree of relative safety. The degree of risk inherent in using any color additive must be compared with the benefit it provides. Where color additives are primarily psychological and cosmetic, acceptable risk should be minimal.

A need also exists for accurate information and labeling at the consumer level to allow consumers to control their intake of color additives. The regulations state color additives are to be identified, but the FDA revised its policy guide in 1985 concerning labeling of colors. The agency approved the terms "artificial color added" or "artificially colored" as informative statements which clearly indicate the addition of color. However, I feel that the regulation should have been enforced as written. Identification of particular color additives would benefit many consumers and alleviate some of the anxiety.

Current color testing is done on animals that are totally protected from drugs, cigarette smoke and alcohol. Testing is also only done on animals that are in the best of health. Color testing is not done on alcoholic animals or asthmatic animals or animals with heart disease. Can we determine the safety of these additives by testing healthy animals in sterile laboratories? Humans have various ailments and live in a polluted environment. Also humans have varying levels of sensitivity to different substances. Individually, color additives might be okay

but, taken together with other chemical additives might cause adverse reactions. Evidence from recent allergy studies indicate that there needs to be additional allergic reaction test incorporated into the current testing procedures. I concur with these findings on allergy testing. If we can do additional testing that will benefit one consumer, then the benefit would be worth the additional cost.

Presently national and international agencies are engaged in the evaluation of the toxicity of color additives. They all document and evaluate the scientific data and publish it for all to use in solving problems relating to the protection of the health and safety of consumers arising from comsumption of these additives. If these same agencies would put together a standard approved listing of color additives for the whole world to use, it could eliminate some problems encountered in importing and exporting food products. It would also alleviate some concerns of color manufacturers in shipping orders and keeping records of what color is approved in which area.

One other area I would like to address is the education and awareness of consumers in the use of color additives. I feel more emphasis should be placed on informing the public of the wide use of these additives and some of the problems that occur from their use. A combined effort by nutrition experts, government agencies (National Institutes of Health, U.S. Department of

Agriculture, and FDA), American Medical Association and the media would be a giant step in this direction. Educational institutes are another source of information on the effects, positive and negative, of color additives. With the new awareness and education, along with the combined efforts of technical experts, consumers might be persuaded that color additives are not as necessary as perceived today.

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