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A Case Study for the Governor's Science Advisory Council: The Nitrite Controversy¹

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The Governor's Science Advisory Council (GSAC) was established by executive order in April 1977 to provide objective scientific advice and information to the Governor or the state agencies. A major problem in science advising to government at all levels is the credibility of information sources. The controversy concerning a possible ban on the use of nitrite in the curing of meat products provided an opportunity for the GSAC to demonstrate its potential as an unbiased representative of the scientific community.

INDEX DESCRIPTORS: nitrite, science advising, Governor's Science Advisory Council, food additives, nitrosamines.

The Governor's Science Advisory Council was established by Executive Order Number 23, April 22, 1977, when Governor Robert D. Ray appointed twelve eminent Iowa scientists to the Council's three panels: Energy, Environment, and Resources. The Council was organized according to a proposal developed by an *ad hoc* committee of the Iowa Academy of Science that served during 1976-77, its work culminating when the Governor adopted their proposal in February, 1977. The record of that committee's work and its make-up are contained in the Academy's annual reports for 1976 and 1977.

The Council is made up of three panels of four members each whose charge is to help provide, on a voluntary basis, objective scientific and technological advice in the areas mentioned above. According to the Executive Order, the Council is responsible to the Governor and is appointed for two-year terms. The Council shall serve at the pleasure of the Governor and, according to the Executive Order, "should be structured so it does not require formal and scheduled meetings. Its purpose is to respond to state government and make available vital scientific and technological information. More formally, the Executive Order lists the the functions of the Council as follows. It shall:

1. respond to the requests of the Governor with objective scientific or technological advice;
2. provide scientific and technological advice to the principal executive departments at the Governor's request or with his approval;
3. identify broad problems in the subjects of energy, environmental quality, and natural resources and at the request of the Governor initiate investigations of such problems and formulate recommendations for their solutions and alleviation;
4. offer objective scientific information and technological advice to the Governor and agencies of government.

The organizational diagram for the Council (Figure 1) shows how the Council is related to the Iowa Academy of Science and the scientific community. The appointees to the Council are listed here according to panel membership:

Energy: Dr. Robert S. Hansen, Chair
Director, Ames Laboratory, USEDOE
Iowa State University
Ames

Mr. David Hodgin
President,
Spectra Associates
Cedar Rapids

Dr. George Skadron
Professor of Physics
Drake University
Des Moines

Dr. Virendra Patel
Chairman, Division of Energy Engineering
Iowa Institute for Hydraulic Research
University of Iowa
Iowa City

Environment: Dr. Richard Bovbjerg
Professor of Zoology
University of Iowa Iowa City

Dr. Clyde Berry
Department of Preventive Medicine
and Environmental Health
College of Medicine
University of Iowa
Iowa City

Dr. Keith Long, Chair
Director, Institute of Agricultural Medicine
University of Iowa
Oakdale

Dr. Richard Van Deusen
Veterinary Service Laboratories
Ames

Resources: Dr. William Brown, Chair
President
Pioneer Hi-Bred International, Inc.
Des Moines

Dr. Roger Bachmann
Department of Animal Ecology
Iowa State University
Ames

Dr. Kenneth Christiansen
Professor of Biology
Grinnell College
Grinnell

Dr. Kenneth Clark
Department of Geology
University of Iowa
Iowa City

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²Executive Director, Iowa Academy of Science, and Liaison Officer, Governor's Science Advisory Council.

THE GOVERNOR'S SCIENCE ADVISORY COUNCIL OF IOWA

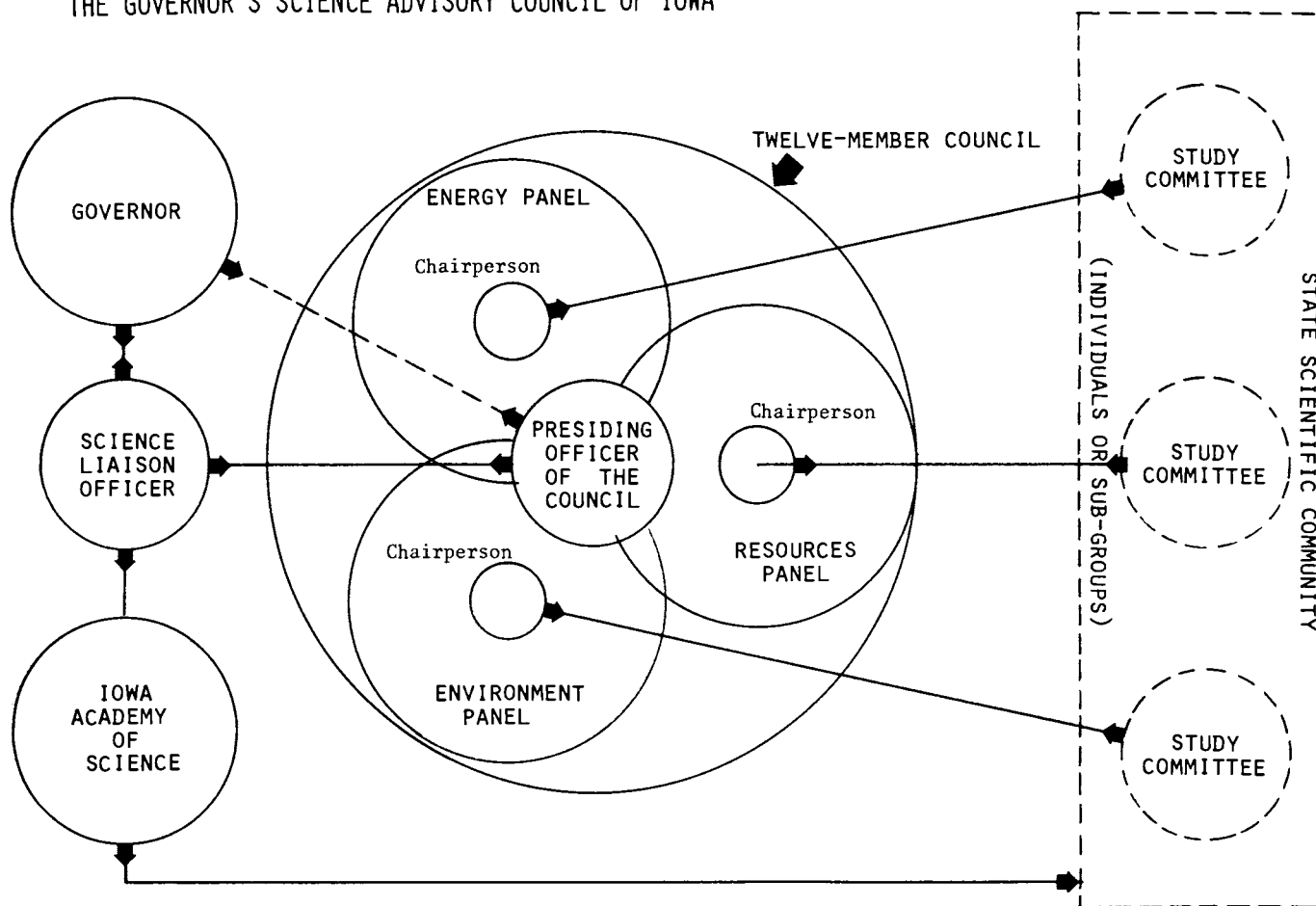


Figure 1. Organization of the Governor's Science Advisory Council.

Contacts with Council members may be arranged through the Liaison Officer:

Dr. Robert W. Hanson, Executive Director
 Iowa Academy of Science
 University of Northern Iowa
 Cedar Falls, IA 50613

The presiding officer of the Council is Robert S. Hansen.

The GSAC was set up to deal with both short-term and long-term issues and to operate in both a reactive and "proactive" mode. In response to a specific request from the Governor's office in the fall of 1977, the Environmental Panel of the GSAC developed a position paper on the question "Should nitrite be banned in the curing of meat products?" The initial reaction to the inquiry by the Liaison Officer was an immediate call to the Council members for information they might have access to and a mailing to all sections of the Iowa Academy of Science that might include persons with appropriate expertise or who might know of such persons. Response was swift and enthusiastic from the Council and the scientific community. Upon receipt of the request from the Governor, on-line computerized literature searches were conducted at both Iowa State University and the University of Iowa. The data bases employed were BIOSIS PREVIEWS, MEDLINE, TOX-LINE, and CHEM ABSTRACTS. Information was obtained on over 1300 articles referring to nitrate, nitrite, and nitrosamines. The articles

were reviewed by Van Deusen and Long of the Council and by Professor Clyde Frank of the Department of Chemistry at the University of Iowa, who acted as an unpaid consultant. The position paper was written by R. W. Hanson (Liaison Officer) from notes assembled by Van Deusen, Long, and Hanson.

The format of the position paper was a matter of consensus among GSAC members and was designed with the following facts in mind: In any attempt to deliver useful scientific information to the makers of public policy there are three phases to consider. The first is the definition of a question or a problem based either on an inquiry emanating from the policy maker or on a concern that comes out of Council discussions. The second phase is the scientific answer or the statement of alternatives related to the inquiry. The third phase is rendering both the question and the answer in terms that are useful to the decision maker.

The position paper on the question of the use of nitrites and nitrates in curing meats is included in its entirety at the end of this article to (a) illustrate one mode of response by the Governor's Science Advisory Council, and (b) present the technical background for the Council's position.

Since the submission of this position paper to the Governor's office, there have been other developments reported in the news media concerning the nitrite question which serve to illustrate the problem of credibility in providing scientific and technical information and advice to policy makers. The attitude of newspaper reporters and columnists is

summed up in a statement by Lauren Soth of the Des Moines Register and Tribune Syndicate which appeared in his column on January 17, 1979, viz: "It is naive to regard any scientific panel as holding a monopoly on truth." (1)

Soth was referring to the Council of Agricultural Science and Technology (CAST) and the fact that it was formed to provide the public and lawmakers with sound information about science and technology in agriculture. Speaking of the make-up of CAST task forces, Soth referred to their "inevitable though unintentional bias", for example, in analysis of the effort of herbicides on the environment "by researchers whose careers are based on developing chemical weed controls." In the case of the nitrite controversy, CAST issued a long news release dated October 4, 1978 (2) accompanied by "Comments from CAST" on the Newberne report that was released after the GSAC's position paper was completed. The Newberne study (3) was used as the basis for a position taken by the FDA-USDA that even without evidence of nitrosamine formation, nitrites produced a statistically significant increase in cancer in rats. The CAST news release pointed out flaws in the study, such as deficiencies in statistical analysis, lack of details about the content of nitrite and nitrosamines in the diets and water consumed, and flaws in the FDA-USDA review of the report and other findings that did not agree with the results of the

Newberne study.

The effect of such controversies within the scientific community on public policy makers is predictable.

The Governor's response to the GSAC's position paper was definitely positive. He appreciated its content but was especially well-impressed with its format. The paper improved the credibility of the scientific community in the eyes of the Governor to a noticeable degree.

The problems of suspected bias and credibility will probably never be eliminated from the participation of the scientific community in public policy formulation. The Governor's Science Advisory Council may stand a good chance of ameliorating these problems.

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- (2) Council for Agricultural Science and Technology, NEWS from CAST, "Scientists Comment on Nitrite Issue", October 4, 1978.
- (3) Newberne, P.M. 1978. Final report on Contract FDA-74-2181: Dietary nitrite in the rat. Dated May 18, 1978. Department of Nutrition and Food Science, Massachusetts Institute of Technology, Cambridge, Massachusetts.

POSITION PAPER

The Question of Using Nitrates and Nitrites in Curing Meats

Governor's Science Advisory Council
February 6, 1978

Question: Should nitrite be banned as an additive in cured meat products?

SUMMARY OF FINDINGS

The Governor's Science Advisory Council, having reviewed the relevant literature, concurs with the following summary of the findings and conclusions of the USDA Expert Panel, as reported by Engel (1):

- a) Nitrosamines have been shown to cause cancer in animals but only at levels considerably higher than those found in meat products.
- b) Bacon contains small quantities of nitrosamines after frying at high temperatures both in the cooked-out fat and the bacon itself. The addition to bacon, during production, of ascorbates or erythrobrates at levels between 500 and 1,000 ppm causes a decrease in the quantities of nitrosamines formed.
- c) Nitrosamines have been produced experimentally in the stomachs of animals under conditions when nitrite and amines are present.
- d) Considering all sources of nitrites, it has been estimated that cured meat products account for about 20% of nitrites ingested by people in the United States. The other 80% come from sources which cannot be readily controlled.
- e) Levels of nitrosamines that have been found in meat products are far below those found experimentally to have induced cancer in animals.
- f) Nitrite inhibits the growth of *C Botulinum*.
- g) Satisfactory substitutes for color, flavor, or preservative ef-

fects of nitrites in many food products have not been found, but studies should be continued to refine and decrease nitrite usage or to find a safe substitute for it.

- h) In the event that such studies continue to demonstrate the need for nitrite in the curing process, decisions on the future use of products cured with nitrite might best be left to the consuming public. Given adequate information as to the risks involved, society itself should be able to determine its willingness to accept them.

COUNCIL RECOMMENDATION

The Governor's Science Advisory Council believes that zero health risk with food additives is a humanly unattainable goal and therefore recommends (a) that nitrite not be banned but the level be lowered to the minimum that still affords protection against botulism; (b) that efforts be continued to find a substitute for nitrite; (c) that the ultimate decision for the acceptability of risk be left with the consumer public.

BACKGROUND FOR COUNCIL POSITION

Food Additives and the "Delaney Clause"

The widespread occurrence of potential carcinogens in the form of air and water pollutants has come to be generally recognized by the general public. The link between tobacco smoke and lung cancer is no

longer debatable. Food additives of any kind are being viewed increasingly with suspicion by the public due to the banning of some of them that had been considered safe for years. Given the current load of environmental carcinogens of natural origin it would seem imperative not to add to the load by using food additives known to be carcinogenic. However, a return to "natural foods" is no guarantee of complete safety. For example, the natural flavor component of sassafras root, safrole, has been found to be carcinogenic; honey has been found to contain a carcinogen coming from pollen, and certain molds on food crops produce toxic substances throughout the world. The food supply of human beings has never been "safe" (2). Two-thirds of the nitrite entering the average human stomach originates in saliva from nitrate in the diet, four-fifths of which comes from vegetables (3). Nitrite (or nitrate that becomes nitrite) can react in the stomach with secondary amines found in or formed from virtually any food that contains protein to form potential carcinogens (4).

The term "food additive" was introduced into federal legislation in 1958. The Food and Drug Administration defines food additives as "substances added directly to food, or substances which may reasonably be expected to become components of food through surface contact with equipment or packaging materials, or even substances that may otherwise affect the food without becoming part of it" (5). The FDA requirements for safety for new food additives are far more stringent than formerly, and the GRAS (Generally Recognized As Safe) list of 670 substances is undergoing scrutiny and revision. The Food Additives Amendment of the Federal Food, Drug and Cosmetics Act contains the "Delaney Clause", which specifies that "No additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animals, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives to induce cancer on man or animals." The Clause has no impact on carcinogens that occur naturally in foods. The Clause is always interpreted as meaning "zero tolerance" for additives that induce cancer. This interpretation ignores the fact that some substances that are carcinogenic at high levels are widely distributed by nature at low, non-carcinogenic levels. Some of these, such as estrogens, are essential for the normal functions of the body (2).

Although the attention given to food additives is relatively recent, it is a matter of record that during the past 40 years gastric cancer in man has steadily decreased in the United States (6,7) even though the consumption of meat products has increased with the standard of living. Non-gastric cancers are responsible for the over-all rise in cancer incidence.

The History of Nitrate/Nitrite as Food Additives

Certain additives have been used for centuries to prevent or retard bacterial spoilage. Some of the earliest include vinegar, salt, sugar, spices, and smoke. More recent preservatives include benzoic acid, esters of para-hydroxybenzoates, and sorbic acid. The use of potassium nitrate as a preservative was well established by the 19th Century, but not until the late 19th Century had chemists found that the color and flavor characteristics of meat cured with nitrate were actually due to nitrite formed from the nitrate, leading to the replacement of nitrate with nitrite in the curing process. The USDA granted regulatory approval for the use of nitrite in 1925, limiting the level to 200 parts per million (ppm) in the finished product, due to the fact that nitrite can be toxic if consumed in excess amounts. The 200 ppm level of nitrite was, however, some 10 times greater than needed for color and flavor (1).

Nitrate and nitrite have been found to have an essential role in inhibiting the growth of *Clostridium botulinum* and are added to meat products to prevent botulism (8). Botulism is generally known to be a potentially fatal condition following a single exposure to 1 or 2 slices of improperly cured bacon, a few spoonfuls of improperly canned beans or mushrooms, etc. Botulism is now so rare in the U.S. that it makes

national headlines when it does occur.

The scientific and popular literature repeatedly expressed concern about the extent and effects of nitrate and nitrite in our diet, dating back to at least 1907 (9). Both nitrate and nitrite themselves are toxic to humans, nitrite being about 10 times more toxic than nitrate. However, nitrate is easily converted to nitrite under physiological conditions, particularly by bacteria in the saliva. The relationship of nitrite and nitrate to infantile methemoglobinemia and other physiological effects is well known (10, 11, 12).

A variety of vegetables, both fresh and cured meat, milk, milk products, and water have been shown to be important sources of nitrate. Nitrates in foods can be converted to nitrites by certain bacterial enzymes. This reaction occurs at room temperature but not at refrigeration temperatures (4). Bacteria normally present in the human mouth convert nitrates to nitrites. It has been shown that 2/3 of the nitrite entering the stomach originates in the saliva; less than 1/3 comes directly from cured meats (3). It is estimated that 4/5 of the nitrate in the human diet is from vegetables and about 1/6 from cured meats, while other sources such as fruit, milk, milk products, and water are insignificant (3).

Prior to the discovery in 1971 of nitrosamines in meat products cured with nitrites or nitrates, USDA believed that the toxicity of nitrite *per se* was the only concern. The report of nitrosamines in these products in the parts per billion (ppb) range caused considerable concern among the USDA-FDA research workers who found them, as well as among the meat industry and consumer groups. In 1972 there were petitions from consumer groups that USDA ban nitrites immediately as cure additives, since nitrosamines were known to be carcinogenic. The petition was denied because of insufficient evidence that nitrite was involved in nitrosamine formation; USDA argued that more information was needed.

In 1973 nitrosamines were found in spice cure premixes by research workers in the Canadian Department of Agriculture. These findings were confirmed by USDA, and such premixes were banned. Since then nitrosamines have been found with regularity only in bacon. Also in 1973 the Secretary of Agriculture established an Expert Panel on Nitrites, Nitrates, and Nitrosamines to advise him if the usage of nitrite and nitrates in curing of meats constituted a public health hazard and, if so, whether such usage should be modified or prohibited (13).

Following a year of study on the safety and continued use of nitrates and nitrites, the 6-member USDA Expert Panel agreed in September 1974 on three broad recommendations (1):

- (1) that nitrate use be prohibited in all cured meats except fermented sausage and dry-cured products.
- (2) that the level of nitrite use in curing meat and poultry be limited to 156 ppm except in bacon and dry-cured products. Action on the latter was deferred pending more research.
- (3) that the current 200 ppm residual nitrite level be reduced in various product categories to reflect what is achievable with current technology.

Another possible source of exposure to nitrosamines from fried bacon came to light in 1975, which prompted the USDA and the Expert Panel to agree that there was a need to address the specific problem of nitrosamine formation in bacon.

A year later, after additional research on bacon was completed, the Secretary of Agriculture announced changes in the 1974 recommendations that included setting lower levels of nitrite and maximum permitted levels of Vitamin C for processing of bacon to block the formation of nitrosamines during frying (1).

The adoption of the Panel's recommendations by the meat industry has been entirely voluntary, according to the American Meat Institute. The USDA has not seen fit to make its 1975 proposal mandatory. In September 1977 the panel drafted a proposed final report (14) recom-

mending nitrite levels for cured meat products that were essentially the same as those recommended in 1975. The Panel concluded that nitrite has been the most acceptable ingredient yet found as an anti-botulism agent and is responsible for the excellent safety record of commercially produced meats. In addition to asking the USDA to propose ranges for nitrite and Vitamin C based on target levels of 120 ppm and 550 ppm respectively, the Panel also recommended that, if carcinogenic nitrosamines are found in any product cured with nitrate or nitrite, the Secretary of Agriculture must seek to eliminate the nitrosamines as rapidly as possible within three years. The USDA has so far failed to make public the final report of the Panel or to issue final regulations incorporating the Panel's recommendations. Rather than accepting the Panel's recommendations, the USDA in October 1977 requested the meat industry to provide information demonstrating whether the use of nitrite in the production of bacon results in the formation of carcinogenic nitrosamines, allowing only 90 days to provide the information. (The USDA recently extended the deadline.) In November, 1977, the Community Nutrition Institute petitioned USDA to ban nitrite from all uses in the processing of meat food products intended for human consumption.

Nitrosamines: Formation, Occurrence, Toxicity

Nitrosamines are relatively easily formed from nitrite or nitrous gases and any secondary amine under conditions usually found in most biological systems depending on whether the nitroso bonding is with nitrogen, sulfur, or carbon atoms of the nitrosating agent. The nitrogen-bonded or N-nitrosamines are of primary concern. Nitrosamines will form in any food which contains nitrite and secondary amines. This has been shown to occur in many vegetables as well as nitrite treated meats or fish. The reaction will occur if these foods are left at room temperature or higher for long periods of time (4,8,15). There is evidence that refrigeration and/or the presence of antioxidants (such as ascorbic acid, Vitamin C) significantly reduces the spontaneous formation of nitrosamines in foods during storage (7).

Secondary amines can be found in or formed by virtually any food that contains protein. When secondary amines and nitrites are present together in an acid environment (such as the stomach) nitrosamines can form (4).

Human health interest in nitrosamines first developed in 1954 when N-nitrosodimethylamine was shown to produce liver disease in human beings (16). Interest heightened in 1956 when the same compound was shown to be carcinogenic in animals (17). Interest was further intensified in 1963 and 1965 when liver toxicity was observed in sheep and mink that were fed diets containing fish meal contaminated with nitrosamine from fish that had been preserved with high levels of nitrite (18,19). Subsequent years were to show that a wide variety of N-nitrosamines produced cancer in a number of species of test animals (20). About 75% of the compounds tested produced lesions in laboratory animals; fully 80% of those tested to date have produced cancer in at least one species of animal (21). Their no-effect levels, limits of toxicity, and margins of safety are unknown. Thus far 140 of the tested nitrosamines have some degree of carcinogenicity when sufficient quantities are administered to susceptible experimental animals. These vary in their potency as cancer-inducing compounds. The most potent thus far reported (N-nitrosodimethylamine) will induce cancer in rats if a dose rate of 0.075 milligrams (mg) per kilogram of body weight is fed daily for 600 days (23). There is no direct evidence indicating carcinogenic activity of these compounds in humans, but there is no reason to believe that humans would not develop some types of cancer if sufficient quantity of N-nitrosamines were consumed (4, 6, 20).

The N-nitrosamines are widespread, having been detected in a variety of substances including processed meats (8, 23), fish (24), alcoholic beverages (25), tobacco smoke (2), air (26, 27, 28), water (29), soil (30), sewage (31), drugs (32, 33, 34) and agricultural chemicals, (35,

36, 37, 38, 39, 40, 41, 42, 43).

The chemical N-nitrosopyrrolidine (N-Pyr) has been isolated from fried bacon (8). The level depends on cooking conditions; recent research has indicated that N-Pyr occurs in fried bacon but not in other cured meat products. The most probably precursor of N-Pyr in bacon appears to be proline, a natural component of many foods which is especially abundant in connective tissue. The formation of N-Pyr during cooking of bacon is not fully understood, but among factors which influence its formation are method of cooking, nitrite concentration, salt concentration, and the presence of ascorbic acid (vitamin C). The latter is a curing accelerator. At present it appears that ascorbic acid and its salts are the best means of inhibiting N-nitrosamine formation.

A recent publication (44) has demonstrated for the first time that the formation of N-nitroso compounds also takes place in the human body after ingestion of precursors. There are then two means by which humans may be exposed to N-nitrosamine — first, by preformed nitrosamines in the diet, and second, by the formation of nitrosamines in the alimentary canal from precursors in the diet (44,45,46).

Precursors of N-nitrosamines

Nitrites as precursors have already been discussed, along with nitrates which become nitrites when ingested primarily through bacterial reduction in the oral cavity.

The other group of precursors includes primary and secondary amines. These occur widely in a variety of plant and animal materials consumed as food by man (2,47) as well as in soil and water as a result of decomposition products (48,29). The process of biological nitrogen fixation and the subsequent formation of fixed nitrogen compounds by plants, microorganisms and higher animals contributes to the amounts of nitrate, nitrite, and amine precursors present in the environment. These conditions can be drastically altered by man, frequently resulting in creating conditions more favorable to the formation of N-nitrosamines. The wide general use of nitrogen fertilizers, pesticides, and nitrification inhibitors in agriculture may result in the accumulation of abnormally high levels of nitrate, nitrite, and amines in the soil (49,50,51).

Written by:

Robert W. Hanson

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for the Governor's Science Advisory Council,
Robert S. Hansen, Presiding Officer

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EDITOR'S NOTE

Since this article was submitted for publication, the author, R.W. Hanson, has reported that the final report for the NSF project cited on page 35 has been completed under the title, "The Iowa Science, Engineering, and Technology Project." One of the consequences of the project was the transferral of the liaison function with the Governor's Science Advisory Council to the office of the Governor's Science Adviser, Dr. Stanley Grant, the Director of the Iowa Geological Survey. Contacts with GSAC members may now be arranged through Dr. Grant's office. His address is:

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 Iowa Geological Survey
 123 North Capitol Street
 Iowa City, IA 52242.