

DRAFT**PESTICIDES**

The use of pesticides in the growing and storing of tobacco may result in the detection of very small residual amounts of these substances in tobacco products. Claims have been made that these residues in cigarettes may play a role in the causation of certain diseases. However, no persuasive scientific studies have been reported which establish that the very small amounts of residues that have been detected in cigarette smoke cause disease in smokers.¹⁻³ Furthermore, extensive government regulation of pesticide use is designed to assure their proper use and application in the growth and cultivation of tobacco.

Pesticides are important agricultural chemicals that are widely used in the production of farm crops throughout the world. The term "pesticide" refers to those chemicals that are formulated and marketed by chemical manufacturers to control a wide range of pests that can cause substantial agricultural production losses. These include insects (insecticides), weeds (herbicides), worms (nematocides), fungi (fungicides), rodents (rodenticides) and other organisms. Accordingly, pesticides make an important contribution to worldwide agricultural success. As a result of approved uses, small amounts of residues from these chemicals are found in virtually all the foods in one's daily diet. Pesticides used in

growing these food commodities are also used in tobacco agriculture.

Pesticides in Perspective

In order to understand the significance of the small amounts of pesticides reportedly found on agricultural crops, it is important to place pesticides and their residue levels in the proper perspective. A pesticide should not be perceived as a health risk simply because it is synthetic or man-made and has been used in agriculture. The mechanism of action that makes pesticides effective in controlling various pests and weeds does not automatically translate into health concerns or an adverse impact on the environment.

To evaluate the possible effect of small residues of pesticides, one must also consider other sources of chemicals that contribute to the array of substances to which humans are exposed. Even though synthetic pesticides are used all over the world, the major source of pest control chemicals is nature itself. All grain, fruit and vegetable plants are known to produce "pesticides" as chemical defenses to infestation by insects, fungi and animal predators. It has been estimated, for example, that one's diet includes about 1.5 grams of these natural "pesticides" during an average day, an amount which has been calculated to be about 10,000

times the amount of synthetic pesticide residues consumed. In other words, 99.99% of the pesticides consumed through the diet are naturally-occurring.⁴

Pesticide Residues on Tobacco

In evaluating the claims about pesticide residues in tobacco, as with the potential hazards associated with exposure to any substance, it is necessary to consider the fundamental toxicological concept that "the poison is in the dose."^{5,6} Any substance given at a high enough dose is toxic, even oxygen and water. Likewise, any substance given at a dose well below its level of demonstrated toxicity would not be expected to result in toxic effects. The applicability of this concept in evaluating any potential effect of human exposure to the extremely low levels of pesticide residues that may be detectable in tobacco is readily apparent.

Tobacco undergoes substantial transformation from the raw leaf to the manufactured cigarette. The levels of pesticide residues that may be found on raw tobacco at the time of harvest are greatly reduced by the time the tobacco is incorporated into the final product. This transformation from the raw leaf to the cigarette is a result of the curing, aging, blending and manufacturing processes employed to produce a finished product

acceptable to the consumer. A significant reduction of pesticide residues occurs during curing, aging and blending. Moreover, steam and heat used in the manufacturing process lead to substantial reductions in residue levels. All of these processing steps and the necessary time lapse that occurs, from harvest of the raw tobacco to the final manufactured product, result in extensive dissipation of the residues.

Even the tiny amounts of pesticide residues that may be present in the final cigarette do not represent the amounts, if any, that may ultimately transfer into mainstream smoke. (Mainstream smoke is the smoke that is drawn through the rod of a burning cigarette by the smoker.) For example, residues of maleic hydrazide that may be detectable in cigarettes do not appreciably transfer into mainstream smoke; a mainstream transfer rate of approximately 0.2% has been reported.⁷ Not even the United States Surgeon General has claimed that the pesticide residues detectable in cigarettes are a proven health problem.^{8,9}

Government Regulation

In many countries, the use of pesticides and the presence of residues in agricultural food commodities are subject to government regulation. These countries have developed pesticide approval standards, based on extensive scientific data, for the

purpose of ensuring that the regulated pesticide residues do not represent a risk to environment or health. The purpose of such government regulations is to ensure the proper use of approved pesticides to enhance crop production without exposing the farmer, the consumer or the environment to risk. It is the practice of the major tobacco manufacturers to purchase and use only that tobacco grown and sold in accordance with the government regulations applicable in the respective countries.

The extent to which governments regulate pesticides varies from country to country. For example, among the European countries, Germany is noted to have a comprehensive set of pesticide tolerances on tobacco and other crops. Many of its neighbors refer to Germany's regulations to govern pesticide tolerance levels in their own countries. The German regulations specify maximum permitted levels on tobacco for residues of many pesticides; the use of other specified pesticides is also allowed if prescribed agricultural practices are followed and the residues do not exceed a recommended maximum amount. These residue levels are applicable to tobacco after it has been processed into the finished product.¹⁰ Tolerances on tobacco have also been set in a limited number of other countries.^{11,12} Between the countries with residue tolerance regulations, there are a number of inconsistencies in the residue levels set for certain pesticides.

The European Community (EC) is expected to consider the issue of tobacco pesticide regulation and may develop uniform standards by 1992. If the EC adopts a directive for tobacco that establishes standardized tolerances, it may include pesticides currently regulated in Germany and other EC Member States.¹²

In the United States, the use of pesticides on all agricultural products, including tobacco, is approved and otherwise regulated principally by the Environmental Protection Agency (EPA). The U.S. Department of Agriculture (USDA) also has certain regulatory responsibilities in this area.¹³ In order for their crops to qualify for the government price support program, U.S. tobacco farmers must certify that they have used only approved pesticides in accordance with specific application requirements.

Advances in Detection of Pesticide Residues

During the last several years, pesticide residues in food and drinking water have been the subject of numerous publications in technical journals and in the lay press. Among the most prominent factors contributing to public awareness on this subject are the tremendous advances in analytical science that have occurred in the last two decades. Technological developments in analytical instrumentation and methodology have made it possible to detect

extremely small residues of pesticides in a variety of commodities that were virtually undetectable only a few years ago.

It is difficult for the non-scientist to comprehend the significance of chemicals detectable at levels of parts per million, parts per billion and parts per trillion in agricultural products, water supplies and other products intended for human consumption. For example, it is important for the public to understand that one part per million is the equivalent of one second in twelve days or one inch in sixteen miles. Soon, analytical methods may make it feasible to detect residues at the level of parts per quadrillion, (the equivalent of 1 inch in 16,000,000,000 miles or 1 second in 32,000,000 years) which may have the effect of further intensifying public concern because it likely will be possible to detect residues in almost everything. Even though technology permits the detection of these extremely small quantities, such findings do not mean that pesticide residues detected at these levels have any significance in terms of health or environment.

The response to media events, such as the finding of Alar (daminozide) residues on apples in the United States, demonstrates that most people are unaware of these facts and illustrates the almost universal and erroneous belief that all pesticides, at any level, are bad. The general public's fear of any detectable amount

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of pesticide residue, however, is seldom justified by the scientific data.

Biological Testing of Pesticide Residues in Tobacco

There are no persuasive studies that establish scientifically that pesticide residues, as they occur in cigarette smoke, cause lung cancer or other diseases in humans. In fact, after decades of research, inhalation studies in which animals have been exposed to fresh whole tobacco smoke have failed to provide experimental proof that smoking causes lung cancer.¹⁴ The reference or model cigarettes used in these animal studies were made from the same inventories of tobacco used in manufacturing commercial cigarettes which would have contained residues of pesticides also found in food and other retail consumer products. In effect, then, pesticides commonly used on tobacco and other crops have been tested in animals by chronic smoke inhalation studies.

In addition, a research project sponsored by the U.S. government's Tobacco Working Group specifically investigated the effects of pesticides in tobacco smoke condensate. This study compared the biological activity of cigarette smoke condensate from specially grown pesticide-free tobacco with smoke condensate from experimental cigarettes grown with commonly used pesticides.

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The results showed no statistically significant differences between the biological activity of smoke condensate from the pesticide-free compared to the pesticide-treated tobacco.¹⁻³

In summary, a comprehensive evaluation of the detectable residues in the cigarette smoke to which the smoker is exposed, the toxicological characteristics of a particular pesticide, and the results of experimental tests with cigarette smoke that contains pesticide residues does not establish a scientific basis for claims that pesticide residues in tobacco contribute to the health risks which have been associated with smoking.

Conclusion

The use of approved pesticides is necessary to achieve efficient and cost-effective production for the farmer and, ultimately, an affordable product for the consumer. Pesticide residues in agricultural products are an unavoidable by-product of the widespread use of pesticides by farmers. Compared to naturally-occurring pesticides in plants, "synthetic" pesticides constitute only a tiny fraction of the chemicals to which humans are exposed in their daily diets. There are no persuasive scientific studies which establish that the very small amounts of pesticide residues that have been detected in cigarette smoke are a cause of disease in smokers.

REFERENCES

1. U.S. Department of Health, Education and Welfare, Public Health Service, National Institutes of Health, Report No. 4. Toward Less Hazardous Cigarettes: The Fourth Set of Experimental Cigarettes, G.B. Gori (ed.), National Cancer Institute, Smoking and Health Program, 1-213, March, 1980.
2. U.S. Department of Health, Education and Welfare, Public Health Service, National Institutes of Health, Report No. 5. Toward Less Hazardous Cigarettes: Summary: Four Skin Painting Bioassays Using Condensate from Experimental Cigarettes, National Cancer Institute, Smoking and Health Program, 1-29, September, 1980.
3. Tso, T.C., Chaplin, J.F., LeLacheur, K.E. and Sheets, T.J., "Pesticide-treated vs. 'Pesticide-free' Tobacco: I. Tobacco Production and Leaf Analysis," Beiträge zur Tabakforschung International 10(2): 114-119, July, 1980.
4. Ames, B.N., Profet, M. and Gold, L.S., "Dietary Pesticides (99.99% All Natural)," Proceedings of the National Academy of Sciences USA 87: 7777-7781, October, 1990.
5. Paracelsus (Theoprastus ex Hohenheim Eremita): Von der Besucht, Dillingen, 1567.

6. Doull, J. and Bruce M.C., "Chapter 1. Origin and Scope of Toxicology." In: Casarett & Doull's Toxicology. The Basic Science of Poisons. Third Edition. New York, Macmillan Publishing Company, 3-10 (see particularly 3), 1986.
7. Haebeler, A.F. and Chortyk, O.T., "Gas-Liquid Chromatographic Determination of Maleic Hydrazide in Tobacco and Tobacco Smoke," Journal of the Association of Official Analytical Chemists 62(1): 171-175, 1979.
8. U.S. Department of Health and Human Services, Public Health Service, Office on Smoking and Health, The Health Consequences of Smoking. The Changing Cigarette: A Report of the Surgeon General, DHHS Publication No. (PHS) 81-50156, Washington, D.C., U.S. Government Printing Office, 55, 1981.
9. U.S. Department of Health and Human Services, Public Health Service, Office on Smoking and Health, The Health Consequences of Smoking. Cancer: A Report of the Surgeon General, Washington, D.C., U.S. Government Printing Office, DHHS Publication No. (PHS) 82-50179, 197, 1982.

10. "Verordnung über Höchstmengen an Pflanzenschutzund sonstigen Mitteln sowie anderen Schädlingsbekämpfungsmitteln in oder auf Lebensmitteln und Tabakerzeugnissen," Bundesgesetzblatt, June 24, 1982, and modifications, April 17, 1984; April 25, 1988, and May 5, 1989.
11. Laws and Decrees, Ministry of Health, Gazetta Ufficiale (Supplement), No. 202, Rome, August 30, 1990.
12. Sheets, T.J., "Current Regulations on Pesticide Residues in Tobacco," Tobacco International 191(18): 21-24, October, 1989.
13. Amendment to 7 CFR Part 29, Subpart B - Regulations, "Tobacco Inspection; Flue-Cured and Burley Tobacco; Importation Prohibitions," Federal Register 54(110): at 24661-24664, June 9, 1989 (codified in the Code of Federal Regulations, Title 7, Part 29, Subpart B).
14. Cross, F.T., Dagle, G.E. and Gies, R.A., "Reply to Dr. Archer's Comment on 'A Histological Study of the Influence of Cigarette Smoking in Suppressing Rn Daughter Carcinogenesis in Dogs,'" Letter to the Editor, Health Physics 56(2): 256, February, 1989.

DRAFT**PESTICIDES****CLAIMS/RESPONSES**

CLAIM: Cigarette manufacturers use tobacco which contains pesticides that are harmful to smokers.

RESPONSE: Pesticides are widely used in the production of farm crops throughout the world, because these chemicals help control insects, weeds, and other pests that cause substantial losses. Consequently, small amounts of residues from these substances are found in virtually all the food we eat. Pesticides used in growing these food commodities are also used in growing tobacco.

There are no persuasive scientific studies which establish that the small amounts of residues that have been detected in tobacco products are a cause of disease in smokers.¹⁻³ In fact, after decades of research, inhalation studies in which animals have been exposed to fresh whole tobacco smoke have failed to provide experimental proof that smoking causes lung cancer.⁴ The reference or model cigarettes used in those animal studies were made from the same tobacco used to make commercial cigarettes which would have contained residues of pesticides also found in food and other consumer products. In effect, then, many pesticides commonly used on tobacco and other crops

have been tested in animals by chronic smoke inhalation studies and have not been scientifically demonstrated to be cause lung cancer.

Furthermore, in response to environmental and health concerns, many governments extensively regulate pesticide use. These regulations are designed to assure that pesticide residues present in food products and other consumables occur at levels which will not result in harm to the consumer.

REFERENCES

1. U.S. Department of Health, Education and Welfare, Public Health Service, National Institutes of Health, Report No. 4. Toward Less Hazardous Cigarettes: The Fourth Set of Experimental Cigarettes, G.B. Gori (ed.), National Cancer Institute, Smoking and Health Program, 1-213, March, 1980.
2. U.S. Department of Health, Education and Welfare, Public Health Service, National Institutes of Health, Report No. 5. Toward Less Hazardous Cigarettes: Summary: Four Skin Painting Bioassays Using Condensate from Experimental Cigarettes, National Cancer Institute, Smoking and Health Program, 1-29, September, 1980.
3. Tso, T.C., Chaplin, J.F., LeLacheur, K.E. and Sheets, T.J., "Pesticide-treated vs. 'Pesticide-free' Tobacco: I. Tobacco Production and Leaf Analysis," Beiträge zur Tabakforschung International 10(2): 114-119, July, 1980.
4. Cross, F.T., Dagle, G.E. and Gies, R.A., "Reply to Dr. Archer's Comment on 'A Histological Study of the Influence of Cigarette Smoking in Suppressing Rn Daughter Carcinogenesis in Dogs,'" Letter to the Editor, Health Physics 56(2): 256, February, 1989.

CLAIM: Pesticides must be harmful, regardless of how little there is in a product. Why else would the media pay so much attention to reports that there are pesticides in food?

RESPONSE: Technological developments have made it possible to detect extremely small residues of pesticides that were virtually undetectable only a few years ago. However, simply because it is possible to detect small amounts of a substance in, for example, a food product does not establish that it is hazardous. The mechanism that makes pesticides effective in controlling various pests and weeds does not automatically translate into health concerns or an adverse impact on the environment. Orchestrated events such as the "Alar scare" in the U.S. suggest that the media may report the news before all scientific facts have been considered.

In this regard, it is worth considering that nature is the major source of plant defense chemicals. Grain, fruit, and vegetable plants have protective mechanisms that produce chemical defenses against infestation by insects, fungi and animal predators. It has been estimated, for example, that an average American may consume about 10,000 times more natural "pesticides" per day than synthetic or man-made pesticide residues. In

other words, 99.9% of the pesticide chemicals consumed through the diet are naturally occurring.¹

REFERENCES

1. Ames, B.N., Profet, M. and Gold, L.S., "Dietary Pesticides (99.99% All Natural)," Proceedings of the National Academy of Sciences USA 87: 7777-7781, October, 1990.