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Findings of Scientific Misconduct

Notice is hereby given that the Office of Research Integrity (ORI) and the Assistant Secretary for Health have taken final action in the following case:

Steven F. Arnold, Ph.D., Tulane University: Based on the report of an investigation conducted by Tulane University, dated July 16, 1999, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Arnold, former Research Assistant Professor at the Center for Bioenvironmental Research at Tulane University Medical Center, engaged in scientific misconduct. Dr. Arnold committed scientific misconduct by intentionally falsifying the research results reported in Table 3 of a paper published in the journal *Science* and by providing falsified and fabricated materials to investigating officials at Tulane University in response to a request for original data to support the research results and conclusions reported in the *Science* paper. In addition, PHS finds that there is no original data or other corroborating evidence to support the research results and conclusions reported in the *Science* paper as a whole.

Specifically, PHS finds that Dr. Arnold's research reported in the *Science* paper involved a finding that environmental chemicals, such as certain insecticides and hydroxylated polychlorinated biphenyls (PCBs), which have a weak estrogenic activity when acting alone, were up to 1000 times more potent in mimicking estrogen when tested in combination. These research results and conclusions were important to the public health because they suggested that the

Environmental Protection Agency (EPA) may need to adjust its guidelines on exposure limits to such chemicals. The *Science* paper was withdrawn on July 25, 1997. [See *Science* 277:462 (July 25, 1997)].

Dr. Arnold has entered into a Voluntary Exclusion Agreement (Agreement) with PHS in which he has voluntarily agreed for a period of five (5) years, beginning on September 20, 2001:

- 1. (1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as defined in 45 C.F.R. Part 76 (Debarment Regulations);
- 2. (2) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

During discussions about the proposed Agreement, Dr. Arnold was cooperative with ORI and accepted responsibility for his actions, admitted to scientific misconduct, and **conceded that there were no original data or other corroborating evidence to support the conclusions reported in the** *Science* **paper.**

REF: Federal Register: October 12, 2001 (Volume 66, Number 198).

<u>Editorial Comment:</u> A few years back when I first learned that Dr. Arnold had withdrawn his paper based on lack of reproducibility, I wrote a short piece for this newsletter praising his integrity for coming forward and admitting he was wrong. The article above indicates that there was more to this than lack of reproducibility. What cannot be seen in the article is the incredible waste of time and resources by people and agencies who tried to reproduce the work, and who promulgated very strict standards and guidelines for testing of environmental hormones, based on the falsified data.

Reports about people who have hidden data showing adverse effects (e.g. tobacco) dominate the media and promote public distrust of industries. This is an example of something at least as sinister and destructive, and hopefully this type of behavior is extremely rare.



DPR Reports Pesticide Use Declined - Again - In 2000

The California Department of Pesticide Regulation reported statewide pesticide use dropped for the second consecutive year in 2000, to the lowest point since 1992.

DPR's preliminary data showed reported pesticide applications totaled about 188 million pounds, compared to 202 million pounds in 1999. Reported pesticide use in California has dropped almost 27 million pounds since 1998.

DPR data showed an overall decline in pounds of chemicals classified as possible carcinogens, reproductive toxins, and toxic air contaminants. Use of two fumigants -- methyl bromide and metam-sodium -- dropped by a total of more than 8 million pounds from 1999 to 2000.

"We are encouraged that overall pesticide use shows a decline for the second consecutive year," said DPR Director Paul E. Helliker. "We always stress that pesticide applications vary from year to year -- depending on weather, pest problems, and other factors -- but we are most encouraged by evidence that farmers and other pesticide users are turning to reduced-risk strategies." He also noted that since 1996, DPR has distributed about \$8.4 million for 200 grants to encourage reduced-risk pest management.

Use of reduced-risk chemicals in 2000 increased by 50 percent, as measured both by pounds applied and acres treated. "DPR has made speedy registration of reduced-risk chemicals a top priority, and these statistics show that the market is ready to accept new products that better protect people and the environment," said Helliker.

Several counties showed significant declines in pesticide use from 1999 to 2000. They include Fresno (down 2.2 million pounds), Stanislaus (2.1 million pounds), Kern (1.6 million pounds), Imperial (1.5 million pounds), Solano (1.3 million pounds), Riverside (1.2 million pounds), Monterey (1.1 million pounds), and San Joaquin (1 million pounds).

Major crops with a decrease in pounds applied included almonds (down more than 3 million pounds), wine grapes (down 3 million pounds), raisin and table grapes (down 2.7 million pounds), processing tomatoes (down 2 million pounds), and carrots and strawberries (each down 1 million pounds).

Other highlights from the preliminary 2000 pesticide use data:

- Use of methyl bromide declined by almost one-third, or more than 4.3 million pounds statewide. Another fumigant, metam-sodium, saw applications decline by 3.9 million pounds. Both fumigants also recorded declines in acreage treated.
- Use of high-toxicity organophosphate and carbamate chemicals declined more than 624,000 pounds from 1999. Cumulative acres treated (one acre treated five times is counted as five acres) declined more than 740,000 acres from 1999.
- Use of chemicals classified as possible carcinogens declined nearly 3.6 million pounds since 1999. Cumulative acreage treated increased about 1.6 million acres.
- Chemicals categorized as reproductive toxins declined nearly 9 million pounds. Acreage increased by about 240,000 acres.
- Chemicals classified as toxic air contaminants declined nearly 3.9 million pounds, while cumulative acreage increased about 500,000 acres.
- Chemicals categorized as ground water contaminants increased by about 100,000 pounds from 1999. Cumulative acreage increased by about 36,000.
- Use of reduced-risk pesticides increased by more than 185,000 pounds and more than 850,000 cumulative acres treated.

In 1990, California became the first state to require full use reporting, and DPR has compiled the reports in the most extensive database of its kind in the nation. Reported uses include production agriculture and postharvest fumigation of crops, structural pest control, landscape maintenance, and other uses. Exempt from reporting are home and garden applications of pesticides, and most industrial and institutional uses.

Summaries of 2000 preliminary pesticide data are available free online at <<u>www.cdpr.ca.gov</u>>. Final data summaries will be posted when analyses are completed. Data summaries from 1990 to 1999 are also available. Each summary includes two versions of the data (one indexed by chemical, the other by crop), with number of applications, acreage or units treated, and pounds of pesticide used. A county-by-county summary of pesticide use is available online.

REF: California Department of Pesticide Regulation -- Press Release, October 23, 2001.



Biotechnology Websites

The EPA's Office of Pesticide Programs Biopesticides website is a comprehensive site for regulatory information about biopesticides. Besides the latest news on biopesticide issues, the website has fact sheets, decision documents, product lists, labels, company lists, study reviews, and bibliographies. The site also has information on regulatory activity available by new active ingredients, new uses, tolerances, experimental use permits, SLNs, and biotech notifications. The fact sheet "What are Biopesticides?" provides a good explanation of biopesticides and how EPA is encouraging the use of biopesticides.

Government Information

Several agencies within the United States Department of Agriculture (USDA) are involved in regulating the use of biotechnology in agriculture. The USDA's <u>Agricultural Biotechnology</u> website is a central point of information about these agencies. This website includes information on permitting and notification procedures, research and trade issues, and laws, regulations, and policies. The website also has an FAQ and contact information and a list of links.

Academic Information

AgBiosafety was recently launched by the University of Nebraska. It is designed to help consumers, educators, students and policy makers understand crop biotechnology. This website contains three sections, the Education Center, Q & A, and GM Crops. The Education Center has educational materials, lesson plans, and basic information on biotechnology. The Q & A section answers frequently asked questions about biotechnology. These questions are answered by experts in biotechnology. The GM Crops section is a database of information on the bioengineered crops that have received regulatory approval in the United States, Canada, and elsewhere. This database, which includes information such as how the crops are produced and what countries have granted approval, is the most comprehensive source in existence. This website was made possible by a grant awarded by the Council for Biotechnology Information.

International Information

The <u>Pest Management Resource Center</u> has developed their Biopesticide website to provide technical and educational information on biopesticides including what biopesticides are available and where they can be obtained within the United Kingdom. The website also has information on related books and journals and links to related websites.

Business/Non-Profit Information

The International Biopesticide Consortium for Development was created to help developing countries to adopt the

use of biopesticides in integrated pest management and sustainable agriculture programs. Their website includes information about the consortium including member information, consortium reports and activities, information about biopesticides, regulatory information, the development process, and a list of links to related websites.

REF: Internet Newsbrief, September 28, 2001.



EPA Provides Guidance on Disposal Instructions for Household Use Pesticides

On September 13, EPA Office of Pesticide Programs (OPP) published a Pesticide Registration Notice (PR Notice 2001-6) revising the 18-year-old guidance. Revised disposal instructions will direct consumers to call their local solid waste authorities for specific instructions and provide state and local governments greater latitude in carrying out their responsibilities for product disposal and waste management programs.

The EPA believes the changes should enhance the proper disposal of pesticide products. The changes include the addition of the phrase "call your local solid waste agency" inclusion of a toll-free telephone number, and removal of the phrase "wrap in paper." Wrapping containers prior to disposal in the trash does not appear to provide reliable protection to sanitation workers and may result in accidental or unknown exposure.

The draft for this guidance has been available since June of 2000. Public response received during the comment period was voluminous, with much of it expressing strong opposition to any label statements directing consumers to put pesticides in the trash. Other commentors demanded additional steps to keep household pesticides out of water supplies.

As of October 2003, OPP will look for the following disposal statements:

On pressurized containers:

- 1. Do not puncture or incinerate,
- 2. If empty: place in trash or offer for recycling if available,
- 3. If partially filled: call you local solid waste agency for disposal instructions.

On non-pressurized containers, statements should say:

- 1. If empty: do not reuse this container. Place in trash or offer for recycling if available,
- 2. If partially filled: call your local solid waste agency for disposal instructions.

Never place unused product down any indoor or outdoor drain. (EPA OPP Update, 9/19/01 & Pesticide & Toxic Chemical News, Vol. 29, No. 48).

REF: Chemically Speaking; October 2001





† Toxicology Tidbits **†**

Imidacloprid

Dr Dr. Allan Felsot, Environmental Toxicologist at Washington State University has written two very informative articles on Imidacloprid: "Admiring Risk Reduction. Does Imidacloprid Have What It Takes?" and "Imidacloprid: Insecticide on the Move."

Link to: aenews.wsu.edu

REF: Agrichemical and Environmental News, October 2001, Issue No. 186.



Pesticide Product Information System

The US EPA's Office of Pesticide Programs <u>Pesticide Product Information System</u> (PPIS) contains information concerning all pesticide products registered in the United States. The files located in this download area are presented in ascii to enable interested parties to access them using a variety of database and spreadsheet software.

REF: FSNET, Oct 5, 2001.



E. Coli Linked to Urinary Infection

Research, conducted at the University of California at Berkeley, based on analysis of 302 cases and published in Thursday's *New England Journal of Medicine*, was cited as finding that food contaminated with a strain of drugresistant *E. coli* has emerged as a possible new source of urinary tract infections.

The story says that *E. coli* is a normal inhabitant of the digestive tract that can cause both intestinal upsets and urinary infections, but while *E. coli* from bad food is a frequent cause of diarrhea and other digestive miseries, urinary tract infections were thought until now to result mostly from inadvertent contact with the victim's own feces.

The new research found that a single, genetically identical strain was responsible for outbreaks of urinary tract infections among women in California, Michigan and Minnesota. Because the germs are exactly the same, investigators assume they came from the same source, and the most likely such source is food.

Researcher Amee R. Manges at Berkeley was quoted as saying, "We were really, really surprised. When we looked at these organisms from these various different women, many of them turned out to be the same. We weren't anticipating that."

REF: FSNET OCTOBER 3, 2001.



NIOSH Issues Farm Youth Death, Injury Data, and Web Information Resource

The U.S. Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) issued two reports with statistics on agriculture-related deaths and injuries among youths on farms. NIOSH also introduced a Web resource for persons seeking information on national efforts to prevent such deaths and injuries.

One of the NIOSH reports, "Fatal Unintentional Farm Injuries Among Persons Less than 20 Years of Age in the United States: Geographic Profiles," DHHS (NIOSH) <u>Publication No. 2001-131</u>, provides regional and state-level data on prevalence of, and factors related to, fatal injuries to young people on farms. This is the first time that such data have been compiled at the regional and state levels. By filling this gap, NIOSH hopes to further efforts by state and community groups to address specific problems in their areas. The report is based on a NIOSH analysis of data from the National Center for Health Statistics for the years 1982 through 1996.

Among other findings, the document on fatal injuries reports that:

- Between 1982 and 1996, 2,174 farm deaths occurred among youths less than 20 years of age.
- Of those deaths, 85.2 percent occurred among males.
- Farm machinery-related deaths were the leading cause of death, accounting for 36 percent of the fatalities.
- In the Northeast and the West, the greatest proportion of farm youth deaths occurred among children age four and under. In the Midwest and the South, the greatest proportion involved youths 15-19 years of age.

The other report, "Injuries Among Youths on Farms in the United States, 1998," DHHS (NIOSH) <u>Publication No.</u> 2001-154, compiles information from a survey conducted by NIOSH and the U.S. Department of Agriculture. Data are presented for the nation as a whole and for different regions of the country and are intended to help safety and health professionals and other groups working in the area of childhood farm safety. Among other findings, the document on non-fatal injuries reports that:

- An estimated 32,808 youth injuries occurred on farms in 1998.
- Youths less than 10 years of age were estimated to have the highest number of injuries (11,210), followed by 12-and 13-year-olds (5,100).
- The leading causes of injury were falls (an estimated 7,225 injuries), off-road transportation incidents (an estimated 5,082 injuries), and being struck by objects (an estimated 3,613 injuries).
- Livestock operations had the highest number of estimated injuries (16,981), followed by crop operations (12,338).

To provide researchers and others with centralized electronic access to a variety of information on preventing death and injury to youths on farms, NIOSH has established a section on its Web page that gathers reports, documents, recommendations, and references in one place. The Web resource is part of NIOSH's ongoing Childhood Agriculture Injury Prevention Initiative, in which the Institute works with the farming community, health and safety professionals, and other agencies to advance efforts to help keep young people safe on farms. The section can be accessed from NIOSH's Web site at www.cdc.gov/niosh, by clicking the link for "NIOSH Childhood Agriculture Injury Prevention Initiative."

The reports on fatal and non-fatal injuries are available in the Web section. For printed copies or other information on NIOSH research, contact the NIOSH toll-free information number, 1-800-35-NIOSH (1-800-356-4674).



FSIS to Post Positive E. coli Sampling Program Test Results on the Internet

The Food Safety and Inspection Service (FSIS) currently provides positive test results from the E. coli O157:H7

microbiological testing program for raw ground beef on an annual basis on its web site. The Agency will now also post positive test results as they are reported from its field service laboratories. In its efforts to protect the public's health and reduce foodborne illness, FSIS began the testing program in 1994, to keep contaminated product from reaching consumers and to spur industry to institute pathogen reduction and HACCP-associated verification programs. Access the data on the FSIS web site at: www.fsis.usda.gov/Ophs/ecoltest/ecpositives.htm.



Anthrax Updates

From the Centers for Disease Control and Prevention

Since October 3, 2001, CDC and state and local public health authorities have been investigating cases of bioterrorism-related anthrax. This <u>report updates findings as of October 31</u>, and includes interim guidelines for the clinical evaluation of persons with possible anthrax. A total of 21 cases (16 confirmed and five suspected) of bioterrorism-related anthrax have been reported among persons who worked in the District of Columbia, Florida, New Jersey, and New York City. Until the source of these intentional exposures is eliminated, clinicians and laboratorians should be alert for clinical evidence of *Bacillus anthracis* infection. Epidemiologic investigation of these cases and surveillance to detect new cases of bioterrorism-associated anthrax continues.

CDC has developed <u>interim recommendations</u> to assist personnel responsible for occupational health and safety in developing a comprehensive program to reduce potential cutaneous or inhalational exposures to *Bacillus anthracis* spores among workers in work sites in which mail is handled or processed. Such work sites include post offices, mail distribution/handling centers, bulk mail centers, air mail facilities, priority mail processing centers, public and private mail rooms, and other settings in which workers are responsible for handling and processing mail. The recommendations are based on the limited information available on methods to avoid infection and on the effectiveness of various prevention strategies. These recommendations will be updated as new information becomes available.

<u>Pregnant women</u> are likely to be among the increasing number of persons receiving antimicrobial prophylaxis for exposure to *B. anthracis*. Clinicians, public health officials, and women who are candidates for treatment should weigh the possible risks and benefits to the mother and fetus when choosing an antimicrobial for postexposure anthrax prophylaxis. Women who become pregnant while taking antimicrobial prophylaxis should continue the medication and consult a health-care provider or public health official to discuss these issues.

From the California Department of Health Services

Recorded non-emergency anthrax-related information and referrals from information technicians are now available from 6:00 a.m. to 9:00 p.m. daily at California's toll-free "Safety Information and Referral Line" at (800) 550-5234. Individuals with hearing impairments can obtain information via the toll-free TTY line (800) 550-5281.

The Department also has several links available on their website http://www.dhs.cahwnet.gov/bioterrorism/> to provide the public with reliable information about biological and chemical terrorism. The Web page will be updated as new information is developed or becomes available.



Availability of Final Recommendations on Reducing the Risk for Transmission of Enteric Pathogens at Petting Zoos, Open Farms, Animal Exhibits, and Other Venues

Final Recommendations on "Reducing the Risk for Transmission of Enteric Pathogens at Petting Zoos, Open Farms, Animal Exhibits, and Other Venues Where the Public Has Contact With Farm Animals" are available on the Internet.

REF: Morbidity and Mortality Weekly Report, October 26, 2001 / 50(42);928.



American Association of Poison Control Centers

A new single nationwide telephone number has been established for the American Association of Poison Control Centers. The number is **(800) 222-1222.** When people call the number, a computer checks the area code and prefix of the caller's number, and routes the call to the nearest center. (USDA-OPMP Newest News, 9/20/01).

REF: Chemically Speaking; October 2001



EPA'S OPP Pesticides in Water Exposure Models are on the Web

Exposure models which the Office of Pesticide Programs (OPP) uses to estimate pesticide concentrations in surface and ground water are now on OPP's Web site at the following address:

http://www.epa.gov/oppefed1/models/water/index.htm. This site contains the user manuals and guidance for running the surface water models, GENEEC2, FIRST, and PRZM-EXAMS, and the ground water model, SCI-GROW. OPP relies on these mathematical models as well as monitoring data to generate pesticide exposure estimates for its drinking water, and aquatic exposure, and water quality assessments.

(The Weekly Report, EPA-OPP September 21, 2001)

REF: Chemically Speaking; October 2001





Food and Drug Administration (FDA) Center for Veterinary Medicine

Antibiotic (Antimicrobial) Resistance and Animals Information for Consumers

The public has expressed concern about the use of antibiotics in livestock and poultry. The following information explains FDA's efforts to deal with the problem of antibiotic resistance due to the use of these drugs in animals. For the entire article please link to FDA's website.

Changing the way CVM regulates antimicrobials for livestock

In November 1998, CVM published a guidance for industry (<u>Guidance for Industry #78</u>) addressing how FDA intends to consider the potential human health impact of the microbial effects associated with all uses of all classes of all new animal drugs intended for use in food-producing animals, when approving such drugs.

In December 1998, CVM published a second document, known as the "Framework" document ("Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals"). This document was published to stimulate discussion on ideas for a new strategy for regulating antimicrobial drugs to ensure the usefulness of human medicines are not lost due to the use of these drugs in livestock and poultry. This document discusses a risk-based approach for regulating the use of antimicrobials in veterinary medicine based, in part, on the drug's importance to human medicine.

Conducting risk assessments

CVM believes that risk assessments can help estimate the risks from the use of antimicrobials in food animals. CVM conducted a <u>risk assessment</u> to help determine the human health impact of fluoroquinolone resistant Campylobacter infections associated with the consumption of chicken. Campylobacter is the most common bacterial cause of diarrhea in the U.S. Fluoroquinolones are a type of antimicrobial drug used to treat human infections including Campylobacter infections.

Conclusion

CVM is taking steps to address the human health concerns associated with the use of antimicrobial drugs in livestock and poultry. CVM is changing the way we manage and approve antimicrobials for livestock and poultry, improving monitoring of the use of these drugs in animals, implementing surveillance systems to monitor bacterial resistance in animals and humans, and conducting assessments of the risks of using these drugs. CVM plans to continue to consult with our stakeholders on this important issue.

REF: FDA Website, October 2001.





