

Cancer Prevention through a Precautionary Approach to Environmental Chemicals
D. Kriebel
School of Health & Environment
Lowell Center for Sustainable Production
University of Massachusetts Lowell
Lowell, MA

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1. Primary prevention of cancer: great potential, little progress

Progress on the prevention of cancers caused by chemical hazards in the workplace and general environment has fallen far short of what is feasible. I will discuss three main reasons for this: 1) public funds dedicated to primary cancer prevention are inadequate; 2) the process of identifying carcinogens in the environment and regulating them is guided by a failed mind-set of one chemical-at-a-time risk assessment which is hopelessly slow and easily subverted by economic interests; and 3) once a hazard is identified, the usual strategy is to reduce exposures through costly and only partially effective engineering controls instead of eliminating the hazard entirely through redesign of the product or process. I will finish with recommendations for how to improve cancer prevention.

Inadequate funding of primary cancer prevention

Public funding for primary cancer prevention – both research and implementation – in the U.S. is shamefully inadequate. There are three levels of prevention: primary, secondary and tertiary. Primary prevention keeps people entirely free of a disease, while secondary prevention helps people who are in the early stages of a disease to be cured more effectively or to suffer fewer symptoms or a milder illness. Tertiary prevention consists of helping people who have an illness to manage their symptoms and to maximize their quality of life while living with the disease. Less than 10% of NCI's budget goes towards prevention, and most of this is focused on screening and early diagnosis – examples of secondary prevention [1]. Current research on true primary cancer prevention is overwhelmingly directed towards lifestyle factors – diet, exercise and smoking. Involuntary environmental and workplace exposures to carcinogens have received very little emphasis in the federal government's research portfolio compared to secondary prevention and individual lifestyle factors.

One justification that it is often cited for this lack of interest in environmental and occupational cancer research is the claim that these are relatively unimportant causes of cancer. I think this is incorrect on three counts. First, the best available evidence suggests that the contribution to cancer from these sources may not be so small. A recent study from the U.K. estimates that a selected set of workplace carcinogen exposures are leading to 8% of all cancer deaths in men and 1.5% in women [2]. This study included only six principal cancer sites and only considered exposures to well-established carcinogens, so it is certainly an underestimate of the total burden. Also not considered were exposures in the general environment like air and water pollution, nor consumer products. Thus the total cancer burden from all environmental and occupational exposures must be substantially higher [3].

Most environmental and occupational carcinogens are chemicals which have been introduced into the environment as a consequence of an economic activity – they are not natural. This means that to a large degree they can be eliminated entirely by redesigning systems of production. This is the second reason that environmental and occupational carcinogens should not be considered a minor problem. In contrast to lifestyle factors which we seek to control through changing behaviors of each citizen, millions of people are protected when a carcinogenic chemical is taken out of commerce. Thus the feasibility of true primary prevention is often considerably greater for these exposures.

The final reason that funding for environmental and occupational cancer research must be dramatically increased is that we remain mostly ignorant about many chemicals to which millions of U.S. citizens are exposed, and it is entirely possible that important preventable cancer hazards remain to be identified. I will discuss this further below.

One chemical at a time risk assessment

Control of occupational and environmental carcinogens in the U.S. is accomplished through a lengthy, costly and usually litigious process of assessing each chemical's risks and developing specific regulations governing its use. This process has become highly politically charged, and in recent years has almost entirely ground to a halt. To limit use of a chemical, the EPA has to provide strong evidence demonstrating risk and must also show that benefits of regulation outweigh the costs. Because of these substantial regulatory burdens, EPA has limited use of fewer than a dozen chemicals in the last three decades. The Occupational Safety and Health Administration has a separate, but no less paralyzing legal process it must follow to limit worker exposures to hazardous chemicals. It too has regulated only a handful of chemicals in the last few decades [3].

I would like to briefly touch on three categories of workplace carcinogenic hazards, and the state of their current regulation in the U.S. A similar presentation could be made about carcinogens in consumer products and the general environment. First are the few well-known hazards for which standards do exist – asbestos, silica and benzene, are examples. Second are lesser-known chemicals that are likely to pose a cancer risk, but for which regulation has not kept pace with the new epidemiologic evidence. Metal working fluids exemplify this group. Finally, there is the problem of the continued introduction and increased use of chemicals whose possible carcinogenicity is wholly uninvestigated.

The known occupational carcinogens. We don't know how many U.S. workers are exposed to carcinogens, but it is likely that there are several million, based on the best available data [3, 4]. Silica is a well-known example of a carcinogen for which exposures continue despite existing regulations. There is now little doubt that silica is a lung carcinogen [5] but nevertheless exposure to high levels of silica, and new cases of silicosis still occur in the U.S. with considerable frequency [6]. An estimated 100,000 workers in the U.S. in 1993 were exposed to silica above the legal limit of 0.1 mg/m^3 , and the situation is unlikely to be any better today. Among these 100,000 workers, there could be as many as 3,000 lung cancer deaths from silica exposure, according to a NIOSH risk assessment [7].

The tortuous history of benzene's regulation is a text book case of how difficult it is to use exposure limits to control a chemical hazard. Benzene's toxicity has been recognized for over 50 years [8]. During that time, the recommended "safe level" of benzene in the workplace has fallen from 100 ppm to 0.5 ppm. Although benzene is no longer used as a solvent in the U.S., it continues to be used in developing countries in precisely the same industrial processes in which it was first recognized as a hazard in the 1940s. In the U.S., as in Europe the population at large is still exposed, as it occurs in gasoline, and in a variety of urban and industrial air emissions.

OSHA attempted to regulate benzene on the basis of newly-recognized epidemiologic evidence of leukemia risk in 1977, by enacting an Emergency Temporary Standard lowering the allowable limit from 10 ppm to 1.0 ppm. The new standard was immediately contested by industries in the courts. The case went all the way to the U.S. Supreme Court, which found that OSHA had failed to show that the costs of the new standard could be justified on the basis of the likely beneficial effects on worker health. As a result, the old standard remained in force for an additional 11 years until it was finally lowered to 1.0 ppm in 1987. It has been estimated that more than 200 additional cancer deaths occurred because of this delay in the standard [8].

The potential carcinogens. As noted above, the U.S. government has created few new standards controlling chemical hazards since the mid-1980's. Thus very little of the cancer epidemiology of the last two decades has led to effective cancer prevention. Many examples could be cited of chemicals for which there is at least a moderate amount of epidemiologic evidence of a cancer risk, but which are not currently regulated with cancer prevention in mind [9]. Such a list might include: 1,3-butadiene causing leukemia, urban air pollution causing lung cancer; pesticides and solvents causing non-Hodgkin's lymphoma, pesticides causing prostate cancer, and metalworking fluids (MWF) causing larynx cancer. The case of MWF is typical. There have been several large epidemiologic studies of workers exposed to MWF, and evidence for increased risk of cancers of the larynx, esophagus, stomach, rectum and bladder. Two large cancer incidence studies have now observed clear evidence of an association between MWF and risk of larynx cancer [10, 11]. But despite this evidence, MWF is regulated as a "nuisance", or "particulate not otherwise classified" (PNOC) – with an occupational standard of 5 mg/m^3 . This standard was not

intended to protect against a cancer risk, but simply to reduce acute irritation from the oily cloud that fills the air in a completely uncontrolled metal machining operation. This is an extremely high exposure level, and most large machining operations in the U.S. voluntarily keep their exposures well below this – between 0.1 and 0.5 mg/m³. While this is a substantial improvement over the legal standard, it is probably not low enough to eliminate the cancer risk. A recent study predicts that larynx cancer risk is approximately doubled after only a decade of exposure at these lower exposure levels [11].

One of the basic limitations in the U.S. regulatory system is that chemicals are essentially assumed to be safe until proven to be hazardous. And, the “proof” of hazard involves not only extensive scientific study, but also lengthy legal battles in nearly all cases. Attempts to adopt standards that would treat classes of chemicals in certain ways without requiring individual risk assessments have failed. There is also no way to shift the presumption of safety for a chemical to a presumption of hazardousness. A consequence of this regulatory approach is that there is no “middle ground” between safe and carcinogenic. There is no way to identify chemicals which may not be known with certainty to be hazardous but which are sufficiently likely to be carcinogens that producers and users should be encouraged to seek safer alternatives.

The great unknown: chemicals that have not been studied for carcinogenicity. Despite these concerns about the lack of progress on known or likely carcinogens, I actually think the larger problem is likely to be the chemicals about which we are entirely ignorant. There are tens of thousands of chemicals in commerce (the exact number is unknown), approximately 2,200 of them considered “high volume”, meaning more than 1 million pounds/year [12]. Unfortunately, this list is not fixed: some 1,500 new chemicals are introduced into commerce each year. Very few of the high volume chemicals have been adequately screened for toxicity. In a perverse “Catch 22”, EPA must demonstrate that the chemical may present an unreasonable risk or significant exposure before it can require producers to conduct toxicity testing. Not surprisingly, fewer than 250 chemicals have undergone mandatory testing since 1980 [13]. A review of the available data on the 3,000 high volume chemicals found that 93% of them lacked some basic chemical screening data, and 43% had no basic toxicity data at all [14]. Only an estimated 2% of the chemicals in commerce have been tested for carcinogenicity in animal bioassays, and of course far fewer have adequate human epidemiologic data [3]. The National Toxicology Program is the principal U.S. government agency charged with conducting toxicologic evaluations of chemicals and evaluating the evidence for carcinogenicity. On average, approximately seven new carcinogens are identified every year. At this rate, the testing cannot possibly keep pace with the introduction of new chemicals.

The Reactionary Principle

The “one chemical-at-a-time” risk assessment approach that has proven to be such an impediment to progress on cancer prevention can be understood more clearly if we name the underlying policy framework: *the reactionary principle* [15]. Under this system, anyone is free to introduce a new hazard into the environment, and governments must wait until an overwhelming body of evidence is accumulated before intervening. Each new regulatory action is challenged with the objective of slowing down or stopping public oversight of production and distribution of chemicals and technologies. We can see the reactionary principle in action in the unconscionable delays in regulating a long list of hazards whose risks were clear long before effective actions were taken to control them: asbestos, benzene, dioxins and PCBs for example [8].

The reactionary principle operates through these key components:

1. requiring incontrovertible evidence of harm for each hazard before taking preventive action;
2. placing the burden on the public (or government agencies) to show that each chemical, material or technology is harmful;
3. not considering potential health and environmental impacts when designing new materials and technologies; and
4. discouraging public participation in decision-making about control of hazards and introduction of new technologies.

In the next section, I contrast this with the precautionary principle, which I believe will be more effective in guiding cancer prevention.

End of pipe doesn't work

Since 1970, the U.S. has required industries to reduce pollution using costly control technologies which remove pollution after it has been created. Similarly, the main strategy for protecting the public and workers is to set "safe" environmental levels of toxic chemicals. These strategies control hazards "at the end of the pipe"; meaning that the hazard is created, but then (at least in theory) removed before damage is done [16]. But it can be far more effective and less costly to remove a chemical entirely from a production process than to try to control it at the end of the pipe. The cost of a control device typically rises exponentially with its efficiency, so that a device designed to remove essentially 100% of a pollutant becomes prohibitively expensive. Also, these control technologies represent an entirely unproductive cost (from the point of view of a firm's profitability), and sooner or later are likely to fail through neglect, or a flagging commitment to safety.

2. What should be done

Precaution

The precautionary principle captures several important strategies for increasing the effectiveness of primary cancer prevention [17]. The definition of the precautionary principle developed for the Rio Declaration of 1989 is often cited (United Nations Environment Agency 1992); and the 1998 Wingspread Statement contains similar language: "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically" [18]. The term "precautionary principle" was introduced into English as a translation of the German word Vorsorgeprinzip. An alternative translation might have been foresight principle, which may carry more of a connotation of anticipatory action, a positive, active idea rather than precaution, which to many sounds negative. The Wingspread Statement lists four central components of the principle:

1. taking preventive action in the face of uncertainty;
2. shifting the burden of proof to the proponents of an activity;
3. exploring a wide range of alternatives to possibly harmful actions; and
4. increasing public participation in decision-making.

The precautionary principle is useful to cancer prevention because it encourages consideration of the public (and broader environmental) good when potentially carcinogenic hazards are being evaluated. When there is uncertainty about the risks and benefits of a proposed activity, the precautionary view is that decisions should be made in a way that errs on the side of caution with respect to the environment and the health of the public.

Sustainable production

Effective cancer prevention begins by eliminating potential carcinogens from our homes, workplaces and environment. The best way to accomplish this is to re-make our economy with technologies which are inherently green and healthy. Clean technologies like solar power and green chemistry are examples of what is called sustainable production [16]. Redesigning our systems of production and consumption to eliminate hazardous chemicals and technologies is more effective than trying to clean up old technologies that use dangerous chemicals. The Massachusetts Toxics Use Reduction Act (TURA) shows how this can be done. The TURA law encourages the use of safer substitutes for toxic chemicals. The law requires industries in Massachusetts to report annually on their use of listed hazardous substances, and to pay an annual fee if they use large quantities of these substances. The law does not directly regulate the use of these chemicals, but simply requires that their use be reported, and that the users file written plans for their elimination. They do not have to carry out the plans. Nevertheless, this largely voluntary approach has had a very positive effect. Over the last decade, Massachusetts companies have reduced the amount of toxic chemicals used in manufacturing processes by 41 %, while reducing costs. Over a six-year period, Massachusetts businesses who implemented projects saved \$12 million [19].

3. Conclusions

Some important lessons have been learned through the U.S. experience in occupational and environmental cancer research and prevention. We have learned that the "one chemical at a time" approach to regulation is not feasible. There are simply too many chemicals in use that lack essential toxicologic data. An entirely new approach is needed. This must include a shift in the burden of proof of safety to the producers of chemicals, so that it is in their interest to demonstrate their safety. This would also involve creating a presumption of hazardousness for classes of

chemicals which are likely to share similar toxicity rather than requiring extensive evidence on each specific chemical.

We have learned that good cancer prevention policy should always be based on scientific evidence, but that the research methods that are chosen to gather this evidence should be appropriate to public health's prevention orientation. A precautionary approach means that decisions about when there is sufficient evidence to act to prevent a hazard will depend on the likely magnitude of the hazard, on the availability of alternatives, and on the economic and political context in which the hazard occurs.

Finally, the history of expensive and only partially successful pollution control programs has taught us that preventing pollution through sustainable production methods is often not only more effective than pollution control, but often more economical as well. Health protection measures which attempt to control, but not eliminate, hazards are rarely effective. The elimination of potentially carcinogenic chemicals is ultimately the only completely effective way to prevent environmental and occupational causes of cancer.

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