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An Overview on Dioxin

By Donald Barnes

(Excerpts from testimony before the Subcommittee on Natural Resources, Agricultural Research and Environment of the House Committee on Science and Technology, June 30, 1983)

My testimony this morning focuses on 2,3,7,8-tetrachloro-dibenzo-p-dioxin (2,3,7,8-TCDD), what is generally considered to be the most toxic of the 75 chlorinated dibenzo-p-dioxins (CDDs). Although other CDDs are present in the environment and are being addressed, most public attention is being focused on this particular dioxin. My remarks are divided into three sections. In the first, I will briefly describe some of the situations in which EPA has been involved with 2,3,7,8-TCDD in the environment. Next, I will discuss the data and the methods we have used to assess the potential for human health effects in these cases. Finally, I will describe some of the gaps in our knowledge about 2,3,7,8-TCDD and the research that would help fill those gaps.

EPA first became aware of the hazards associated with 2,3,7,8-TCDD through laboratory animal studies conducted in the 1960s and early 1970s. At that time, the scope of the Agency's "dioxin problem" was defined by the presence of 2,3,7,8-TCDD as an unavoidable contaminant in certain pesticide products. During the 1970s, the Agency took action to restrict the use of certain of these pesticide products and to obtain more information about the toxicity of 2,3,7,8-TCDD and analytical methods for detecting its presence in the environment. Some of these efforts involved extensive cooperation between EPA, various academic institutions and environmental groups, other Federal agencies, and industry. By the end of the decade, this cooperative venture had succeeded in developing a reliable method to detect TCDD in some media in the low parts per trillion range. (One part per trillion is roughly equivalent to the thickness of a human hair compared to the distance across the United States.)

Donald Barnes is Science Advisor to the Assistant Administrator for Pesticides and Toxic Substances. He has been chairman since 1980 of EPA's Chlorinated Dioxins Work Group, which has been assisting in the coordination of EPA's involvement in dioxin-related matters. Barnes has also been EPA's representative on the Cabinet Council's Agent Orange Work Group.

In 1979, based on extensive animal data and epidemiologic information, the Agency took emergency action to suspend certain uses of 2,4,5-T and Silvex, two pesticide products which contain 2,3,7,8-TCDD. That ban remains in effect at this time.

Also in the late 1970s, the Agency took action in connection with a series of dumpsites along the Niagara River in New York, some of which were found to contain 2,3,7,8-TCDD wastes. These wastes were found along with a range of other hazardous substances which had resulted from previous manufacturing operations in the area. During the same time period, the Agency provided technical assistance in the successful cleanup of a smaller dioxin-contaminated dumpsite in Missouri.

By 1979, the possibility of a range of dioxin emissions from combustion processes had become an issue. During this period, the Agency carefully investigated the question of the emission of 2,3,7,8-TCDD, other TCDD isomers, and tetrachlorinated dibenzofurans (TCDFs) during the combustion of polychlorinated biphenyls (PCBs) at two hazardous waste incinerators in the midwest.

In 1980 and 1981, the Agency participated on a United States team, headed by the Food and Drug Administration (FDA), which met with Canadian officials to determine the presence of 2,3,7,8-TCDD in fish in the Great Lakes, assess the significance of these findings, and discuss ways to reduce or remove any sources of contamination.

In 1980, the Agency issued a rule that requires 60-day notification to EPA prior to the disposal of most 2,3,7,8-TCDD contaminated manufacturing wastes. This 60-day period gives the Agency the opportunity to assess the risks associated with the proposed disposal and to take action if those risks are judged too unreasonable.

In 1981, furthering its assessment of the emissions from combustion processes, EPA completed a series of studies of TCDD emissions during the combustion of municipal wastes. TCDDs, including small amounts of 2,3,7,8-TCDD, were detected at four of five facilities sampled. An interim evaluation of the significance of these TCDD emissions for human health was issued in November 1981, and it was concluded that the emissions "do not present a public heal hazard for residents living in the immediate vicinity" of the facilities tested.

More recently, the Agency has been acti in identifying sites in several states, predominantly in Missouri, which have beer contaminated with 2,3,7,8-TCDD as a consequence of manufacturing activities or the injudicious disposition of wastes.

Finally, I would like to mention that an EPA Task Force on Dioxins, with represent tives from several program offices, is currently developing an overall strategy which will recommend specific actions and coordination mechanisms to address the wide range of dioxin questions. The top management at EPA now has this strategy under review.

I have included this chronology neither t seek commendation nor to evoke sympathy but rather to illustrate that the Agency is n stranger to 2,3,7,8-TCDD and the challenge it presents to those required to make decisions regarding unreasonable risks to human health and the environment.

The data base on 2,3,7,8-TCDD toxicity extensive, but certainly not exhaustive. Mu of what we know has been obtained from animal studies. For example, we know that the material is lethal to a variety of animal species when administered in single, small doses (less than a millionth of a gram in some species). We know that there is a 1000-fold range of toxic response among various species in these lethality studies. W know that 2,3,7,8-TCDD is carcinogenic in rats and mice at very low doses (via both ingestion and dermal absorption), resulting a variety of tumors in these animals. We know that, as a carcinogen, it can at least behave as a promoter, a compound capable of eliciting frank carcinogenesis in animals which have been previously exposed to oth carcinogens, and as a cocarcinogen. We know that the compound can interfere with reproductive success in females, especially pregnant ones, of several species (including rats, mice, rabbits, and monkeys), often at very low doses. We know that the material can affect elements of the immune system in test animals. In addition, there are a

number of other effects which have been observed, including organ damage (for example, to the liver and thymus), metabolic disruptions, and significant enzymatic changes.

In the area of human health effects, our folder of known information is somewhat slimmer. This is partially due to the fact that most human data are obtained from occupational exposure and industrial accidents. In these cases, it has been difficult to estimate the level of 2,3,7,8-TCDD exposure in individual cases or to distinguish the effect of concommitant exposure to other chemicals. In any event, there is general agreement in the scientific community that chloracne, a persistent, acne-like condition which can be disfiguring but which is not life-threatening, is associated with persons acutely exposed to 2,3,7,8-TCDD. Chloracne can also be evoked by a number of chlorinated hydrocarbon chemicals in addition to 2,3,7,8-TCDD. Other effects which have been associated with these exposure incidents, and which are generally considered to be short-term, include liver dysfunction, effects on the immune system, and various neurological complaints.

A series of reports has associated human exposure to 2,3,7,8-TCDD-containing chemicals and a rare form of cancer, soft tissue sarcoma. This possible link was first reported in a pair of studies of Swedish workers, and additional, but not definitive, support for the association was found by re-assessing studies completed here in the United States, in which isolated cases of soft tissue sarcomas have been found in 2,3,7,8-TCDD exposed populations. However, other studies both here and abroad have failed to confirm this association. This possible association is being explored in a number of current or planned studies by various government agencies.

In considering risk, one must remember that it is a function of two variables: hazard and exposure. A reduction in the size of either variable will result in a comparable reduction in risk. For example, even the most hazardous substance will be of no risk, if its exposure to people and the environment can be reduced to zero. In evaluating risk, the Agency combines hazard information (data on inherent toxicity) and exposure data to arrive at quantitative estimates of risk. To illustrate, I will briefly discuss how the Agency assesses carcinogenic and reproductive effects.

The Agency assesses the excess risk of cancer using the methods of the Cancer Assessment Group (CAG), whose guidelines were published in 1976. Briefly, the Agency first examines the data base to make a determination as to whether the chemical substance is a carcinogen. In addition to the qualitative question, a quantitative extrapolation to low environmental doses is performed in order to estimate a rough upper bound for the risk, using a linear, non-threshold procedure. This presumes that the initiation of cancer is a non-threshold phenomenon; that is, there is some risk, perhaps very small, at any exposure above zero. In the case of 2,3,7,8-TCDD the Agency has based its quantitative analysis primarily on the linerarized, multi-stage extrapolation model, although several others have also been used on occasion. It should be pointed out that these procedures result not in an absolute prediction of the risk, but rather a "ballpark" estimate of the upper limit of risk which we do not believe will be exceeded. The actual risk is likely to be some value less than this upper limit, possibly zero. These extrapolation procedures indicated that 2,3,7,8-TCDD was quite potent compared to many other carcinogens evaluated using the same techniques.

The magnitude of the risk depends heavily on the level of 2,3,7,8-TCDD to which people are exposed and the likelihood that this exposure results in an absorbed, toxicologically active dose. Usually, we do not have definitive information on human exposure. In lieu of such data, the Agency makes certain assumptions, usually of the "reasonable worst case" variety, so as to err on the side of public safety. For example, in the case of TCDDs emitted from combustion sources, the Agency assumed that a person might spend his entire life at the spot of highest estimated ground level concentration, that all TCDDs inhaled would be retained, and that TCDDs attached to particles would be completely biologically active. "Reasonable worst case" estimates of exposure, when combined with the extrapolation results, lead to an estimate of the upper limit of risk.

In contrast to cancer, the Agency has generally regarded reproductive hazard as one for which there exists a level of exposure below which it is not expected that an adverse effect will occur, the so-called "threshold assumption." In assessing this type of risk, the scientist uses an adequate study in which an administered dose level resulted in no observed adverse effects (NOAEL) in test animals and compares it to the generally smaller level of estimated human exposure. The ratio of the NOAEL to this estimated human exposure is referred to as the margin of safety.

In the case of 2,3,7,8-TCDD, the Agency used a study in which rats were followed over three generations to determine the effect of 2,3,7,8-TCDD on the reproductive success of the animals. Although the authors of the study reported that no consistent adverse effects were observed at the lowest dose tested, EPA scientists concluded that statistically significant effects were observed at that dose and that the study lacked sufficient statistical power to conclusively demonstrate a NOAEL. This issue has been the source of considerable debate. Therefore, in comparing the lowest dose tested to the estimated exposure dose in humans, the Agency speaks of a "confidence ratio," instead of a "margin of safety."

In recent decisions associated with the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA, or "Superfund"), the Agency has also made use of risk evaluations generated by the Centers for Disease Control (CDC). In general, CDC uses methods which are comparable to those of the Agency.

In a typical 2,3,7,8-TCDD-related situation, Agency scientists provide decisionmakers with the results of a risk assessment; i.e., estimated upper limits of cancer risk and confidence ratios for reproductive effects associated with various exposure scenarios. The assumptions and limitations of the approach should be explicitly stated. At this point, risk assessment ends and risk management begins.

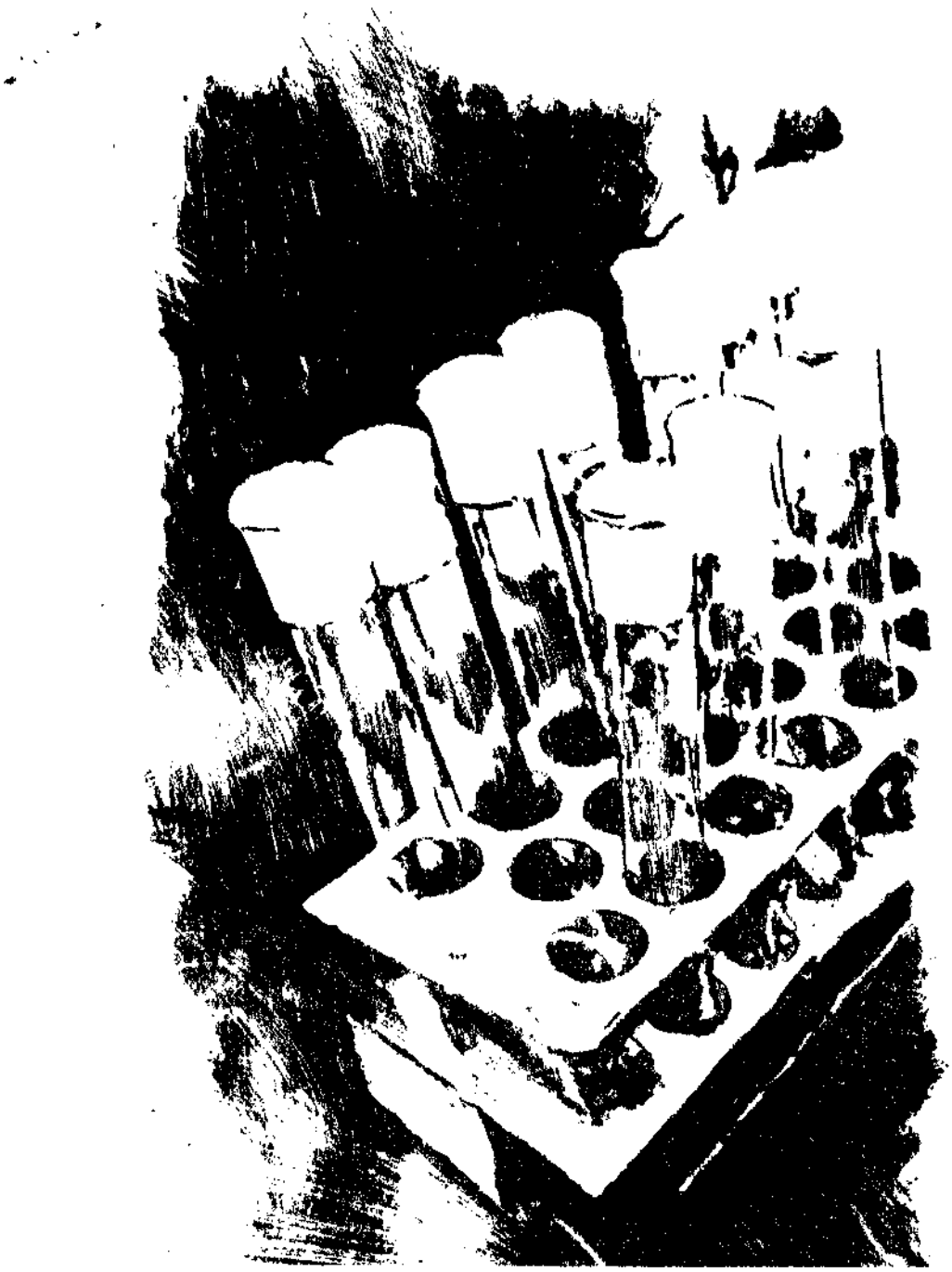
The distinction between risk assessment and risk management has been highlighted in the recent report of the National Academy of Sciences (NAS) entitled *Risk Assessment in the Federal Government*. Generally, risk assessment is an objective, scientific evaluation of the magnitude of the risk, independent of considerations of what should be done about that risk. Risk management is the decisionmaking process, involving more subjective, societal judgments which consider certain non-risk factors when selecting an appropriate response to the risk. In a speech delivered at the NAS, EPA Administrator Ruckelshaus emphasized this difference, stating that the two processes should remain separated within a regulatory agency.

In its letter of invitation to these hearings the Subcommittee has asked EPA specifically, "What evidence on the effects of dioxin on human health justifies establishing a dioxin concentration standard of one part per billion in soil and how should such a standard be interpreted and used?" I believe your question may have been promoted by EPA's recent relocation action under "Superfund," and EPA welcomes the opportunity this hearing affords to clarify what has been erroneously characterized by some press reports as an EPA "safe" level of dioxin.

First of all, there is no simple level which will give rise to equivalent risks in all cases. Even if one were to decide on an acceptable level of risk, the key question of exposure must be addressed on a site-specific basis before making any estimate of an acceptabl level of contamination in the soil. For example, a decisionmaker could conclude that greater than 1 ppb of 2,3,7,8-TCDD in the soil of one person's front yard might represent an unreasonable risk, since such a person might not be expected to easily or reasonably limit his exposure to this soil. That same decisionmaker could conclude, however, that many times that level is acceptable in an isolated spot at a manufac turing site or at the bottom of a reclaimed dumpsite where people are unlikely to be exposed. In sum, the determination of an acceptable level is dependent upon many factors, and it is an oversimplication to seek a universally applicable level.

Second, the act of establishing a level is no longer in the realm of risk assessment; instead, this is the province of risk management. In assessing risks, scientists can, for example, present the decisionmaker with a graphical summary illustrating the possible range of risks associated with various exposure scenarios and contamination level in the soil. In reaching the risk management decision, the decisionmaker weights all the elements of the risk assessment; i.e., the qualitative case, the quantitative case, the exposure assessment, and the limitations a uncertainties involved. In addition, the decisionmaker factors in non-risk considera tions, which might include feasibility and cost of clean-up, possible alternative action consistency with regulation of other risks, and concerns of the affected community. In sum, while the scientists may agree that a certain spectrum of risk is associated with different levels of contamination and exposure, precisely where on that spectrum a decisionmaker determines the appropriate level to be will vary as factors specific to a given situation are considered.

Thus, EPA has not adopted a generally applicable action level for "Superfund" purposes; rather the Agency continues to make decisions on a site-by-site basis, takin into consideration both the CDC health advisories and any special on-site circum-



stances in determining action at individual sites.

Finally, I would like to address some of the gaps in our scientific knowledge about toxicity of 2,3,7,8-TCDD in the environment and what type of research would improve the scientific data base for decisionmaking.

1. Toxicity of 2,3,7,8-TCDD in complex mixtures

Most of the data generated to date has been with 2,3,7,8-TCDD alone. In the environment, however, we usually encounter the compound in combination with other materials and associated with particulates; e.g., soil or fly ash. The effects of dioxins in the presence of these other materials need to be investigated to answer questions of synergism and bioavailability. Promising techniques for assessing "TCDD equivalents" of such complex mixtures should be developed further.

2. Exposure issues

We need to know more about the ways 2,3,7,8-TCDD moves in the environment; e.g., possibility of volatilization, bioaccumulation from soils into fish, dermal penetration, and the amount of soil children might ingest.

3. Disposal/destruction methods

Currently, adequately tested and practical methods for disposal and/or destruction of dioxin contaminated materials are limited. Much work remains to be done to determine how best to deal with this material once it has been discovered in the environment.

4. Epidemiological studies

Various Federal agencies are now conducting epidemiological studies to investigate the possible effects of 2,3,7,8-TCDD in humans. There are additional studies which could be conducted, involving populations near more recently discovered contamination sites.

5. Background levels

It would be helpful to know the background level of 2,3,7,8-TCDD in various parts of the environment, such as land, various foods, and human tissue. This information could serve as valuable benchmarks.

6. Related compounds

There are 74 other chlorinated dibezno-p-dioxins and 135 chlorinated dibenzofurans, some of which are also of concern and appear in the environment. Activities need to be encouraged to deal with these compounds on a rational, deliberate basis.

7. Mechanism-of-action studies and pharmacokinetics

Important information is currently being deduced about the first stages of toxicity induced by 2,3,7,8-TCDD and related compounds. As we obtain more fundamental knowledge about what is happening at the molecular and cellular level, the possibility of our being able to understand exactly how and why 2,3,7,8-TCDD exerts its toxicity increases. This information may help us explain the basis of the species variability and where humans fall in this range of reactions. Moreover, we may then be able to assess the toxic potential of literally hundreds of related toxic chemicals without devoting to each individual compound the mass of resources we have had to dedicate to 2,3,7,8-TCDD.

As a final word, I would like to observe that it is important that we keep the dioxin problem in a proper perspective. I believe we need to address the dioxin issue in a rational, deliberate manner. At the same time, we should not permit this legitimate concern to cause us to neglect other legitimate concerns, such as those embodied in the pools, pits, and lagoons of abandoned dumpsites, the emission of toxic pollutants into our air and water, and the potential for unreasonable risks associated with chemicals to which we are exposed daily. As scientists and regulators, we have an obligation to maintain a balance among all of these concerns. □

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