functions, thermal and electrical conductivity data, magnetic susceptibility, optical constants, and magnetooptical effects are generally included. Data on molecular structure have become very important; the rapidly developing field of spectroscopic methods has become of especial interest in this connection. However, the complete review and reporting of the many papers dealing with these subjects can rupture the framework of a Handbook of Inorganic Chemistry. The Gmelin Institute uses guidance provided here by its professional staff in order to achieve a practicable way for describing the properties of the substances—in the characteristic and complete Gmelin form—without becoming mired in details and in speculative discussions. The professional staff also counsels the Institute as to selecting the chemical elements and compounds to describe in the Handbook.

As publishers of the Handbook, the Gmelin Institute is in contact with organizations which are active in the fields of documentation and information. Close contact with the Beilstein Institute follows directly because of proximity. A relationship with Landolt–Börnstein is also maintained; arrangements are being established to prepare a common Index. The "Fach-Informations-Zentrum Chemie" (Technical Information Center for Chemistry) is also located at the Carl-Bosch Haus; the major organizations in Germany active in documentation and information are affiliated with this Center, which is organizationally responsive to the "Internationale Dokumentationsgesellschaft der Chemie" (International Documentation Society for Chemistry)—created by the large chemical companies. The West German Federal Government through the Ministry for Research and Technology is also a partner of the Center. The Technical Information Center for Chemistry is in very close contact with Chemical Abstracts Service, and the Gmelin Institute uses the magnetic tapes of *Chemical Abstracts Condensates*. This is another example of international collaboration.

I opened with the question: "What should a chemist do when he wishes information on a chemical or physical subject?", and I stated that many possibilities existed to answer such questions. One of the possibilities for information exchange is that of personal correspondence. This form of direct communication is surely not the worst; it is in widespread use and often is successfully practiced—otherwise there would be no more conferences or congresses. Following personal correspondence comes information exchange in the form of publications. This covers the entire spectrum of publications ranging from conference proceedings, laboratory reports, preliminary releases, articles, progress reports, review studies, monographs, and abstracts up to the multivolume Handbooks. Among these latter publications, the Gmelin Handbook of Inorganic Chemistry occupies a very special place.

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Health and Safety Information for Regulatory Purposes — An Industrial Point of View

JAMES W. CONDER

Health and Environmental Sciences, The Dow Chemical Company, 2030 Dow Center, Midland, Michigan 48640

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This article describes how one company (The Dow Chemical Company) is managing the issue of increasing demands by regulatory agencies for health and environmental information. Described are: an interdisciplinary organization linked by a resource and communication network; methods of evaluating information requests and establishing priorities for response; and problems in communicating with the regulators. The need for a responsive technical dialogue between government and industry is stressed.

Much of the data used by the government in developing health and safety regulations originates in industry. Increasing demands by government agencies for toxicity studies, exposure data, process and emissions information, environmental effects, and related information impose burdens on individual companies far beyond the mechanics of data generation, compilation, and retrieval. Such demands raise the additional consideration of direct costs, allocation of technical resources to "nonproductive" efforts, and protection of proprietary information. There also exist possibilities of misuse or misinterpretation of the data by government agencies, or, conversely, failure to use relevant information in regulatory decision making.

Regulatory agencies seem to have an insatiable appetite for data. The front end of the regulatory process is structured for information collection, storage, selection — and occasional usage. Since much of the government's data originates in industry (although frequently transmitted via contractors), effective and reliable communications between government and industry are vital.

Only ten years ago, the transmission of technical data to federal regulatory agencies was fairly simple. It was conducted through established channels for registering agricultural products, food additives, and pharmaceuticals, or through peer relationships between industry and government scientists.

However, with the increased regulatory activities of such agencies as the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA), the data demands on industry have increased significantly. Transmitting technical data for regulatory purposes now requires a major level of company effort and internal consistency if it is to be managed properly. The current complexity, number, and frequency of federal agency information demands on a technically based company can require a major allocation of that company's available resources.

Consistency in this article is provided by the following definitions: "information" is considered synonymous with "communication" and implies the evaluation and utilization of data; "regulatory purpose" relates to the development of health and environmental standards by OSHA, by the Na-

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Table I. Typical Agency Data Uses[a]

- Health standard criteria development–NIOSH
- Field studies; hazard evaluations; control technology research–NIOSH
- Health standards development and rule-making–OSHA
- Definition of emission/effluent levels–EPA
- Determination of best available control technology–EPA
- Clearances for agricultural chemicals–EPA
- Various reports under the Toxic Substances Control Act-(TSCA)–EPA

[a] For health and environmental information.

Table II. Types of Data-Information

- Chemical and physical properties
- Toxicity studies (animal)
- Metabolism and pharmacokinetic studies
- Toxicity studies (environmental)
- Exposure levels (occupational and environmental)
- Medical surveillance data
- Epidemiology
- Bioaccumulation, environmental persistence, and movement data
- Analytical methods
- Emission/effluent flow and composition
- Control technology
- Cost data

tional Institute for Occupational Safety & Health (NIOSH) and by EPA.

The approach taken by Dow starts with an examination of these questions:

- What is the intended use of the information required?
- Should the company respond to specific requests, and if so, what should the nature of that response be?

We find it necessary in our evaluation of requests for information to focus on one paramount question:

- Will our efforts to provide regulatory agencies with sound technical information contribute to reasonable health and environmental standards?

Frankly, at this time we are dissatisfied with our answers to that question.

There is more to the total company effort than simply managing information demands, company resources, and confidentiality. There also is need to assure that the information supplied to an agency is correctly interpreted and used for decision making, and is not merely collected and stored.

Table I illustrates typical uses which government agencies attempt to make of industry data. Organizations such as NIOSH, OSHA, and EPA must be assisted to understand the technical aspects of the substance to be controlled, the nature of the industry(s) using that substance, and the range potentials for human exposure. Even though many regulators will insist that they are dealing with social policy rather than science, health and environmental standards must have a sound scientific and technical foundation.

Certain standards may be the performance type, listing a specific emission or effluent level, but not designating a specific type of control. Standards may also be of the process or work practice type, with certain procedures mandated by the regulation. The latter standards may attempt to designate "Best Available Control Technology" or require specified operational procedures. Frequently, health and environmental standards may be a combination of these types. An example is seen in OSHA's efforts to regulate exposure to coke-oven emissions or benzene through a combination of permissible exposure limits, work practices, and engineering controls.

Table II lists some of the data and information useful for informed decision-making by an agency. To assess the need for regulation and ultimately to determine the content of any proposed standard, a regulatory agency should consider all data relevant to potential hazard, feasible control, and potential impact of a regulation. That agency must be familiar with the chemical and physical properties of a substance; must be prepared to evaluate (or accept evaluations of) various animal and environmental toxicity studies, metabolism, and pharmacokinetic data; and must understand the fate or persistence of the material in the environment. Available data from medical surveillance and epidemiological studies should be used in assessing the risk or hazard from human exposure to chemical substances.

However, for environmental standards, the current state of control technology and analytical methodology is frequently the final regulatory determinant. Technology-based standards seem simpler for the regulatory agencies to develop than health-based standards. This is leading to increasing federal interest in private industrial process technology, an interest we believe is often inappropriate. Government insistence on information on actual emission and effluent flows, composition data, or even a complete description of current control technology results in serious problems and confrontations over proprietary information.

Similar problems in identifying practical need, proprietary privilege, and intended use occur when cost data must be developed and reviewed so the most cost-effective control mechanism can be selected (or at least considered).

Yet another area of sensitivity between government and industry is the availability of personnel and medical records. Regulatory agencies insist that they need access to personnel and medical records to conduct or evaluate epidemiological and hazard surveillance studies. There are, however, important legal and ethical barriers to revealing such information outside the medical community. These issues are still being resolved, both in court and directly between the parties involved.

There are common problems and needs shared by regulatory agencies and private industry. There are also areas in which the two seem adversaries. Regardless, when responding to such complex information demands, a company must be prepared to manage the accumulation, evaluation, and handling of both the agency requests and company responses.

For a company to manage the requests and flow of information between itself and regulatory agencies, there are at least three sequential steps.

First, there must be an accurate inventory of company resources, including data bases and resource people. Such resources will predictably cross organizational lines, involving elements from research, manufacturing, marketing, employee relations, and other functions.

Second, there must be established a flexible, interdisciplinary organizational approach to data handling, evaluation, and transmittal. Generating data requires specialists, but evaluation of data requires an interdisciplinary effort. Effective information flow within a company allows timely, accurate responses outside the company.

Third, there must be a clearly understood mechanism for evaluating regulatory agency requests and for providing an appropriate response. Whether the request is directed to an operating division, a sales office, or company headquarters, the receiving group must know how to "plug it into the system". There can be no question about who in the company has responsibility to determine exactly what data are requested, whether the requestor (agency or contractor) is entitled to the data, and what the nature of the response will be.

A technically oriented and responsible company must do more than generate, collect, and transmit data. In addition to laboratory and library facilities, that company must possess (or develop) the expertise for evaluating the actual hazard from a given substance under actual conditions of use. Note that the hazard of a material depends not only on its toxicity, but also on the nature and condition of probable exposure. This

type of evaluation is essential for use by the company as well as by regulatory agencies.

A company's resources must be able to use the evaluated data both internally and externally: internally for the safety and health of their own work force, customers, or the general public; externally by participating in the regulatory and the public arenas. External activities should include assisting in the development of sound health and environmental standards.

For the type of information requests most commonly made of the chemical industry, necessary resources include expertise in toxicology, industrial hygiene, occupational health, environmental testing, and analytical chemistry.

The company must have an interdisciplinary mix of specialists and research capabilities able to function in the regulatory process. The ultimate data package, consisting of evaluated information, should be balanced, representing both laboratory and practical inputs. Frequently, government agencies over-rely on data from epidemiologists and toxicologists, ignoring input from process chemists or engineers. When we recognize that the actual hazard attributed to a substance is a function of exposure potentials as well as chemical, physical, and biological properties, then the roles of the physical scientist and engineer are recognized as being equally important.

There are possibly as many organizational approaches as there are companies. Even so, there are three features that we consider essential to a sound program, regardless of the actual physical organization involved. There must be enough *flexibility* to allow rapid decision-making with the highest degree of professional judgment. Decisions will be made at various points and must be immediately communicated throughout the organization. This leads to the second feature—*decentralized decision-making*. A health professional charged with the safety and health of a company's operating division cannot be expected to await decisions from corporate headquarters. He has to have the expertise and the authority to make and execute a judgment.

Finally, it is important that the health and environmental organization in the company be so structured that "*communications forcing*" is both normal and demanded. The toxicologist must talk to the industrial hygienist; the industrial hygienist must talk to the process engineer, etc. All involved specialists must understand both the toxicology and biomedical aspects of a given material, and the impact of proposed regulation. A flexible, decentralized organization permits and encourages this type of exchange of information.

The Dow Chemical Company relies on a communication and resource linkage known as the Health and Environmental Sciences Network. We have informally linked all of our global areas, our operating divisions, and our centers of technical expertise (such as Toxicology, Industrial Hygiene, Medicine, and Environmental Sciences). This network (seen in Figure 1) also includes the related management, legal, safety, and government relations functions. Thus, all our centers of expertise can be tapped quickly, with decisions made and transmitted rapidly. Internally, new hazard information can be communicated throughout the company in a matter of hours through preestablished contact points.

With the aforementioned resources and organization necessary for handling the many regulatory agency requests for data, other managerial needs also can be satisfied. Within Dow, each request for information is evaluated on a case-by-case basis. Each is examined for its individual merits, resource demands, and what, if any, potential benefit to Dow. In some cases, compliance is required by law or regulation; in others, some degree of discretion is permitted.

These factors also must be carefully considered:

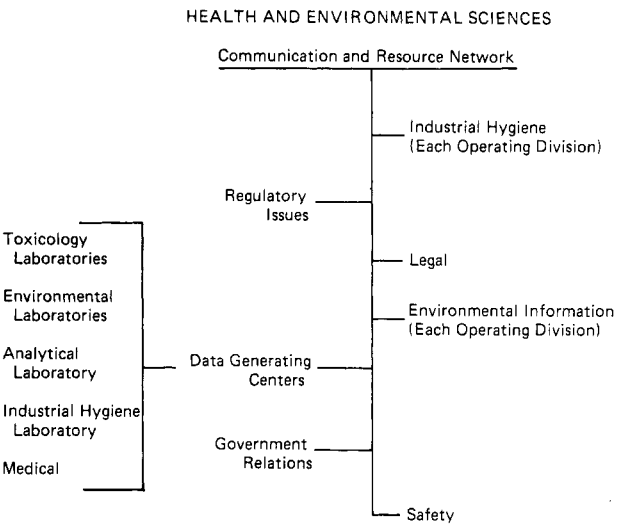

Figure 1.

(1) Should the resources necessary to generate the information be allocated to this specific request? For instance, having toxicologists on your staff does not make them necessarily available. Priorities must be established.

(2) Will there be a problem of individual employee privacy? The availability of personal medical and health records is a highly visible and unsettled regulatory issue.

(3) Is there a problem of protecting proprietary information? Particularly in the chemical industry, proprietary information and "trade secrets" may be the difference between a successful operation and a loser. There is constant conflict between the regulator's desire to know how a company processes materials, and that company's need to protect such information from possible release to the public and its competitors.

(4) Is the requested information likely to be used appropriately by a government agency? Does the requesting agency have the necessary expertise to evaluate and responsibly use the data supplied? Is the information being collected for its own sake, or does the agency intend to use it in decision making? Industry scientists expend much time and effort — at great cost — in responding to requests for technical information, or review of criteria documents drafted by a federal agency, only to find their responses often ignored.

To illustrate the levels of effort involved in responding to government requests, we can review Dow's participation with NIOSH in preparing a criteria document for seven vinyl compounds. The NIOSH intent to develop criteria for a health standard was published in a *Federal Register* notice. Our prepared written response included a variety of toxicology studies, extensive industrial hygiene data, the results of epidemiological studies, and data from our medical surveillance program, which spanned many years. Further, our toxicologists orally presented research data and conclusions at NIOSH headquarters.

This effort was then followed by a plant visit to production sites by the NIOSH contractor, who requested information on our processes, work practices, engineering controls, training program, occupational exposure data, medical surveillance program, analytical methodology, and other relevant aspects. We contributed data and operating experience both verbally and in written form. We also participated in a thorough, lengthy review of the draft criteria document.

The continuation of such intense efforts by private industry will depend on whether or not the agency seriously considers such technical input in their decision-making process.

Another example of agency-industry cooperation (and conflict) is seen in a review of the Dow efforts in a recently promulgated OSHA standard for regulating acrylonitrile in

the workplace. First, OSHA published a detailed proposal in the *Federal Register* and invited public comment. This was followed by a lengthy hearing in Washington, D.C. The Dow involvement included a written package containing information similar to that provided for criteria development. It included our analytical methodology, toxicological studies, industrial hygiene data, process descriptions, economic evaluations, work practices, training programs, medical surveillance data, and other information. Dow scientists also testified at the hearing and engaged in the cross-examination of expert witnesses. Dow involvement was extensive. Between January and July of 1978, we invested over 1 $^1/_2$ man years of effort on this one topic.

Because of environmental concerns, Dow receives many requests for information from the Environmental Protection Agency. These relate to air and water standards, emission data, feasibility studies, and other factors. For instance, certain requests for information on water effluents are commonly referred to as "308 letters". Such a letter requests data on our effluent flows and composition, performance of pollution control devices, pollution control costs, and concentration of various pollutants (known as priority pollutants). We expect well over a hundred such requests this year. One such "308 letter" (although happily not typical) is certainly worthy of mention. It was 23 pages long, involved nine plants, and required our compilation of over 6000 different effluent stream analyses. Our final response was over 500 pages long and required an investment of more than 1700 man hours.

Such requests demand more than just willingness to cooperate. If compliance is to be responsible, they require enormous expenditures of technical talent, time, and dollars, which should be directed to the highest priority needs. Add to these examples additional requests for air emissions data (seeking to define emission levels and to determine best available technology), and the magnitude of this informational problem is obviously both a challenge and a burden. It is essential that a company's resources be very carefully allocated in responding to such requests.

The problem of balanced and reasonable technical interface between industry and regulatory agencies grows increasingly complex. Based on the Dow experience to date, several areas can be identified for significant improvement if our country is to receive proportional value from the efforts expended.

From industry, there must be a continuing commitment to reasonable regulation. While the efforts required to generate data-based responses for use in setting standards are significant, so are the potential rewards. If such regulations are based on both data and experience, they should be the most reasonable regulations obtainable.

From industry, we need greater realization of the need for flexible and responsive management of demands for health and environmental data. This is important because of problems in allocation of company resources and protection of proprietary or sensitive information. Equally important is the need to influence regulation with sound science.

From industry, it is vital that a high level of technical credibility be maintained by providing reliable data and experience to the regulators.

From government agencies, we would like greater opportunity for technical dialogue. The present method of establishing standards relies on written requests for information followed by adversarial proceedings. This lack of dialogue represents one of the most frustrating experiences in the whole regulatory process. The only answer industry may ever receive to a written position or submission of data is the final regulation. Public hearings are not technical dialogues. The most effective time for technical communication is *before* a regulation is drafted, not while it is being defended.

From government regulatory agencies, we ask greater selectivity in their demands. Agency requests for all information relating to a list of 1500 chemicals, or for all information relative to establishing a standard for the "petrochemical industry", are useless exercises. There can be no meaningful response to such a vague or generic request. There is no way that meaningful regulations can evolve from such nonselective efforts.

From government agencies, we ask that data be demanded only when the data will be used in the decision-making process. There is no justification for creating massive — and grossly expensive — data banks for possible future use. Industry is very apprehensive that EPA's apparent authority to collect data under the Toxic Substances Control Act will be used indiscriminately and will provide little of value in preparing reasonable, necessary regulations.

Finally, we suggest that both industry and government must agree that the real issue is not regulation vs. nonregulation. The issue is reasonable regulation vs. overregulation. If dialogues are established and if the data bases supplied to the government are pertinent and sound, then the eventual outcome should be reasonable health and environmental standards.

The United States' Hazardous Waste Regulatory Program†

JOHN P. LEHMAN
U.S. Environmental Protection Agency, Washington, D.C. 20460

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Key elements and status of proposed national standards for hazardous waste regulations and program implementation issues are described.

The United States is developing a new hazardous waste regulatory control program as mandated by the Resource Conservation and Recovery Act of 1976 (RCRA), which amends the Solid Waste Disposal Act. Subtitle C of RCRA requires the U.S. Environmental Protection Agency, in consultation with State governments, to develop national standards for: hazardous waste definition; generators and transporters of hazardous waste; performance, design, and operating requirements for hazardous waste treatment, storage, and disposal facilities; a permit system for such facilities; and guidelines describing conditions under which State governments will be authorized and assisted to carry out the hazardous waste control program. The Federal EPA must implement the program in States which do not seek, or do not qualify for, authorization. Local governments, citizens' groups,

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