

# Interagency Regulatory Liaison Group Role in Phthalates

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## Introduction

In its attempt to regulate interstate commerce of chemicals within the United States, Congress created five regulatory agencies with the burden of overseeing various aspects of that trade. The Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC), the United States Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) the U.S. Department of Labor and its Occupational Safety and Health Administration (OSHA) and the Food and Drug Administration (FDA) regulate the use of chemicals in interstate commerce. Because each of these agencies arose through different enabling legislation and are concerned with a different use of chemicals, it is likely that the same chemical would be independently regulated by two or more of those agencies. In addition, because chemicals and their manufacture and use, in general, are a concern of each of those agencies, policies and requirements for safe use of those chemicals could be different for each agency. For the above reasons, in October 1977, at the urging of the executive branch, each of the agency heads of EPA, CPSC, FDA and OSHA agreed to recommend those specific areas in which interagency cooperation would be beneficial to all agencies. Some areas of concern were finally agreed upon by the agency heads.

In the area of toxicity testing guidelines, it was important for each agency to require similar standards to prevent duplicative testing by industry. Cooperation could result in a development of standardized testing guidelines which, if utilized in a toxicity test, would be acceptable for safety standards among the agencies. Joint research planning was another area where common interests could be identified. Each agency could avoid unnecessary

duplication in spending for research already being performed by another agency. The third area was information exchange. The objective was to improve the quantity and quality of information available to each agency. Risk assessment was a fourth area identified since it is essential that health and safety decisions among agencies be made in a uniform manner. It is also important that risk assessment made by uniform decision making, identify potential problem areas. Fifth, it was also believed that an inspector from a single agency could observe the same territory as many inspectors from different agencies had previously. This attempt to coordinate inspection efforts was believed to increase the efficiency and reduce the burden of inspection on industry and government. Sixth, the agency heads wanted to determine if there were sufficient resources that could be pooled to develop a uniform federal government agency response to problems of common concern to two or more agencies. Communication and education were considered important because it was felt that information transmitted to the public on toxic substances should be consistent, accurate, and educational. The development of a uniform policy for review of epidemiology data was the eighth area where the agency heads felt that there was common interest.

In October 1977, the agency heads formally announced the creation of the Interagency Regulatory Liaison Group (IRLG). The stated goal of that organization was "to increase the public health and protect the environment by sharing information, avoiding duplication of effort and developing consistent regulatory policy while reducing the burden on those regulated and the agencies themselves (1).

It was decided to concentrate on research for regulation of hazardous substances on a nationwide basis. Some operating concepts are to avoid creating another level of bureaucracy, to focus on action, not studies. Coordination is the rule, not the exception. It was deemed important to be certain

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**Table 1. Chronology of development of Interagency Regulatory Liaison Group (IRLG) comprising Consumer Product Safety Commission, Environmental Protection Agency, Food And Drug Administration, HEW, Food Safety And Quality Service, USDA, Occupational Safety And Health Administration, DOL.**

Date	Step
August 2, 1977	Announced intention to form IRLG
September 26, 1977	Signed agreement
October 11, 1977	Published agreement in <i>Federal Register</i>
February 17, 1978	Published work plans in <i>Federal Register</i>
March 2-6, 1978	Work groups held public meetings
January, 1979	FSQS joined IRLG
May 22-23, 1979	Agency heads held public meetings

that arrangements make good sense and to emphasize quality regional coordination.

In September 1977, an interagency agreement was signed by each agency head to commence this newly created "Confederation of Agencies." Draft work/action plans were prepared and published in the *Federal Register* in February 1978 (2). Finally in January 1979, the Department of Agriculture/Food Safety and Inspection Service, as it is now known, joined the IRLG (Table 1).

## Organization of IRLG

IRLG as a group of agencies has only one fulltime employee. This is to reinforce the idea that agency employees are also members of the IRLG. Each member agency designates part of its operating budget for the funding of IRLG programs.

The IRLG is directed by the five agency heads. Day-to-day activities of the agencies are overseen by two surrogates from each agency. The substructure below the surrogates consists of regional staff, task groups, work groups, senior headquarters staff and operating staff, but there is no set organizational hierarchy as to how these groups interact. The organization is flexible to allow for unexpected emergencies where one group will be required to interact with another.

Regulatory development is one of the groups within working groups. It is a work group consisting of 20 subwork groups which each are concerned with a chemical of concern to at least two of the member agencies (Table 2). Twice a year each work group publishes a report on their activities in a free booklet called *The Regulatory Reporter*. Copies of the *Regulatory Reporter* are available from EPA;

**Table 2. Work groups and counterpart groups.**

Work Groups	Counterpart Groups	Regions
Epidemiology Information Exchange	Budget Compliance and Enforcement	I: Boston II: New York
Regulatory Development	Congressional Affairs	III: Philadelphia
Testing Standards And Guidelines	Contracts	IV: Atlanta
Education Task Force	Economists	V: Chicago
	Freedom Of Information	VI: Dallas
	General Counsels	VII: Kansas City
	Personnel	VIII: Denver
	Planning and Evaluation	IX: San Francisco
	Public Information	X: Seattle
	Regional Coordinators	
	Research Planning	

Office of Pesticides and Toxic Substances; Industry Assistance Office; 401 M Street S.W.; Washington, D.C. 20460, (800) 424-9065 and in Washington, D.C. 554-1404.

## The Phthalate Workgroup on Plasticizers

Soon after the results of National Cancer Institute Carcinogenic Bioassay on di(2-ethylhexyl) phthalate (DEHP), di(2-ethylhexyl) adipate (DEHA) and butyl benzyl phthalate (BBP) became available in draft form, it became apparent that each of the member agencies of IRLG would be concerned about the results and possibly interested in future reregulation of those compounds based on the NCI data.

IRLG immediately responded by forming a new work group on plasticizers. Each Member agency appointed a representative (it should be apparent that if a particular agency had no interest in the regulation of a compound, it would not appoint a representative). Because of the diverse interests in plasticizers, the work group has had representatives of a number of non-IRLG agencies, including the Department of Defense (DOD), the National Toxicology Program (NTP), The National Institute of Occupational Health and Safety (NIOSH), and the Nuclear Regulatory Commission (NRC), attend its meetings. The work group agreed that DEHP, DEHA and BBP were of primary concern; however, any possible alternative for those compounds would also fall within the review by the work

group. It was also of general consensus that all toxicology and exposure data available within an individual agency would be exchanged so that the same data base would be considered by all involved.

It was obvious that the data base for toxicity studies on phthalates was large. However, the only long-term studies on phthalates other than the recent NCI studies were completed in the middle 1950s. Although negative in terms of carcinogenicity, those studies were not conducted under present day testing standards. It was a concern of the IRLG scientist representing each agency that advice from outside the U.S. government on the generally accepted interpretation of those results be sought out. As a result, the work group agreed that a conference consisting of recognized experts in the field of phthalates and carcinogenesis could provide the work group and member agencies enough background on manufacturing, exposure, toxicology and testing rationale data so that regulatory decisions on the matter could be made by each agency.

Agreements were made between the NTP and IRLG who sponsored this conference on phthalates. The work group felt that a conference held prior to

commencement of any formal regulatory action would allow participants to freely air their views without a cloud of pending regulatory activity which might restrict the free flow of ideas.

The information gained from the conference is presently being considered by the agencies and work group. The information was valuable and helped the work group understand many of the issues involved with the problem.

The workgroup is now continuing its efforts by working with the NTP and the Chemical Manufacturers Association to develop a clearinghouse for ongoing toxicological studies being conducted throughout the world. This program is presently being initiated and it is hopeful that it can prevent duplication of experimentation by scientists throughout the world and continue the open dialogue for discussion of the interpretation of these new results.

#### REFERENCES

1. Fed. Reg. 42: 54856-54857 (1977).
2. Fed. Reg. 44: 54648 (1979).