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Establishing Regulatory Priorities

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Abstract

PAST EFFORTS TO IMPROVE the effectiveness of regulatory activities have met opposition from two directions: the criticism of the details of administrative procedures recommended for use, and the conflicting goals of various constituencies. Congress has failed to establish consistent national priorities or goals for regulatory action, but has provided specific mandates which often are conflicting in their purpose. The regulator must in many cases make a decision whether to regulate or not, and if so, to what degree, despite these obstructions. There is a need therefore for a method by which the potential universe of regulatory candidates can be divided into manageable groups according to the need for control. The strengths and weaknesses of various past efforts to establish regulatory priorities are discussed, and the broad outline of a procedure is described; which will assist in assigning the needed priorities to reasonably sized groups of candidates, both within agencies and on a national basis.

Introduction

It is not helpful to a regulator simply to reiterate the difficulties and shortcomings of the existing methods for estimating either the relative or the absolute risk posed by a candidate substance. There are times when political pressures, statutory mandates, or occasionally, the finding that a substance is more hazardous than was thought previously, require that a regulatory decision must be made. The responsible regulator wishes to make this decision in the

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context of the spectrum of risks presented by other potential candidates, and therefore needs a means of comparing the risks of this substance with that of others on the agenda.

Many procedures for making this comparison have been proposed and tried. The National Cancer Program conducted its bioassay studies for many years on a priority schedule which was derived from an evaluation of the importance of a particular chemical by a panel of experts who considered, among other criteria, the extent of exposure and the probable hazard of the substance. A numerical value representing this evaluation was used to place the substance in the testing schedule. A very similar ad hoc value judgment is used by the Interagency Testing Committee (ITC) to discharge its mandate under Section 4 (e) of the Toxic Substances Control Act. [1] Public comment and input also are utilized in this screening program.

The Environmental Protection Agency (EPA) engaged contractors to survey the universe of airborne organic pollutants for candidates. [2] This resulted in a priority list of 43 substances [3] chosen primarily because of exposure estimates, from which individual chemicals have been selected for regulatory consideration under a proposed airborne carcinogen policy [4] after a prelminary evaluation of the carcinogenic risk of that chemical. [5]

The Occupational Safety and Health Administration (OSHA) established criteria for screening the current literature [6] for potential carcinogens and produced a candidate list [7] from which it also is to choose a priority list for regulatory consideration.

None of these methods has met with great success. The EPA has expended tremendous effort in literature surveys and other studies in order to determine if the substances on the ITC list requires further testing, and at one time had fallen years behind the statutory schedule for making this decision. [8] The philosophy of the proposed carcinogen policy failed to withstand scientific scrutiny the first time that it was tested. [9] OSHA had the foundation of its program destroyed by the Supreme Court decision in the benzene case, [10] and has halted further regulatory action in this area while reconsidering the policy. [11]

The National Research Council Report

The Committee on Environmental Decision Making of the National Research Council (NRC) evaluated the rulemaking processes of the EPA, and recommended [12] a more goal-oriented and quantitative approach than that which was found at the Agency. An effort to implement this recommendation resulted in a contract between the EPA and the NRC to study the feasibility of applying that approach to the Pesticide Program.

The NRC Committee which was charged with this task quickly came to the realization that the EPA was faced with an insurmountable task in attempting to quantify the risk to humans or the environment of some 500-plus active ingredients which are utilized in over 35,000 formulations. Even had there been adequate data for these risk estimates, the logistics were overwhelming for the preparation of the preliminary risk estimates, even without any consideration of alternatives or benefits. [13]

The NRC Report contains many other sound, reasonable, and undoubtedly useful recommendations. There is no question that the call for a greater familiarity of the staff with pesticide manufacture and use will be helpful in regulatory evaluation. The recommendation for the presentation of the results of risk estimates, as both the most probable and the reasonable upper bound values, is sound. The realization that society as a whole pays the cost and reaps the benefits of regulations is fundamental, but often overlooked. The establishment of external review panels with the appropriate expertise for evaluating both risks and benefits is reasonable. Implementation of these proposals should improve the efficiency of the pesticide program greatly, and serious consideration should be given to the applicability of similar programs in the other agency offices.

However, the keystone of the Report is the ordering of the task into a manageable array by determining the relative toxicity and exposure of the active ingredients. It is this segment which will be discussed below, particularly its applicability to chronic hazards in general, and carcinogenicity in particular.

The problem for the regulatory agencies has been increased by the mixed signals they have received from Congress. For example, the Delaney Clause forbids any consideration of potential benefits from the use of a substance suspected of being an animal carcinogen, and of the costs of foregoing the use of that substance to society, while the Toxic Substances Control Act and the Federal Insecticide, Fungicide and Rodenticide Act require the use of cost-benefit analysis, and the Clean Air Act is silent on the subject. A rational ordering of national priorities can come only as the result of Congressional direction, but in the meantime the regulatory agencies are bound to follow their current mandates. Efforts along the lines suggested by the NRC Report will be of great value in organizing this effort.

Some Major Regulatory Problems

The need for establishing priorities to handle a large universe of potential candidates has long been recognized by the EPA. It faces this problem in every office of its structure, toxic substances,

hazardous wastes, airborne pollutants, water contaminants, and so on. It has resisted a case-by-case evaluation of the hazard of a particular substance, and because of administrative convenience has looked at production levels, [14] number of persons exposed, [3] ability to detect [15] or some other surrogate for potential risk to the environment, rather than the characteristics of the substance itself. It is here that the NRC proposal, in recommending a case-by-case evaluation of the need for regulation after a priority list has been developed, is unique, and potentially most valuable.

However, the task is only made more manageable, and not necessarily any simpler, by taking this approach. As the NRC Report points out, the data base will not become more reliable, nor the interspecies extrapolation more rational, by the application of a particular mechanism for their consideration. We still are unable to extrapolate risks for animals with any precision much beyond the observed dose range, despite the availability of extremely large data bases [16] and much additional information is necessary before any approximation of human risk from animal data is possible.

The determination of relative risk even within the animal data base will be a complex problem because of interspecies, strain, colony, and interlaboratory differences. One proposal, for example, has been that a specific point on the dose response curve, such as 50% tumor production (T_{50}), be taken as the comparative datum. [17] Even this simple assessment is fraught with problems. As the potency of the substance varies in comparison to its acute toxicity, the T_{50} point assumes various positions relative to the Maximum Tolerable Dose (MTD), and thus may be more or less affected by the animal life span. At the same time the pharmacokinetics may be varying as various metabolic pathways approach saturation. Using a lower tumor yield as the datum will reduce the severity of these effects, and will move the comparison point closer to the dose of interest, but the basic problem remains.

Similarly, there is the question of whether all "excess tumors" should be considered, or only fatal tumors, or only tumors of certain organs which are thought to be relevant to both the test animal and humans. These effects also often are variable as dose level changes.

Similar problems exist in the consideration of whether the design of the original experiment was suitable for this type of evaluation, or whether it is proper to compare data in this manner for a broad variety of classes of compounds with perhaps different mechanisms of carcinogenesis or dose response curves. These problems exist, in fact, for almost any other particular feature of the data base.

Resolution of these problems can be obtained by careful evaluation of all of the available scientific data for each substance, and in some cases, development of additional facts. Resources are not available, and political pressure often does not allow the necessary time to do this properly for all candidate substances simultaneously.

Separation of the candidate list into categories according to the degree of apparent need for control is necessary to make the task possible.

A key feature of the NRC Committee recommendation is that the substances should be considered for regulation in the order determined by the relative toxicities, not that they be regulated in that order. The report then goes on to describe some of the factors which are to be developed by the experts in preparing the data for this consideration by Agency management. These include evaluation of the relative toxicity of the major pesticides from animal data, estimating human risks where reliable epidemiological or other relevant data are available, and determining probable exposure from the most likely uses of the pesticides over its probable economic life, and under various regulatory options. Benefits of use are to be estimated and reviewed by an external panel separate from that which reviewed the scientific data. All of this effort is combined into a presentation for Agency management to use in making a decision as to the need for, and possible extent of, regulation of that substance.

The Separation of Scientific and Political Phases

This is the second major feature of the NRC recommendation, the explicit separation of the scientific and sociopolitical phases of regulation. The NRC proposal is aimed at preparing the decision package for agency management consideration, and not at the final decision itself, and turns its efforts toward assuring that the best possible scientific data base is provided for determining whether or not to proceed.

Past Agency efforts have failed in part because of insistence that the final decision to regulate be included in the preparation of the preliminary package, thus forcing an intermingling of scientific and sociopolitical considerations at a premature point. This also led to a temptation to present only those scientific data which supported the preformed decision.

A regulatory decision should be the result of at least three classes of consideration. First, a substance becomes a candidate because of statutory requirements, political pressure, or data suggesting reasons for concern. The proponent of the regulation then will prepare a data package containing the relevant facts, and the interpretation of those facts as they apply to the candidate. This leads to the ability to prepare the first level of recommendation, and sometimes the matter will stop there, or be deferred until more urgent needs are met.

Thus, if the facts point toward an immediate need for regulation, the scientific data base should be reviewed by an independent body

of scientists competent in the appropriate fields to determine the soundness and completeness of the data, and for an estimation of the actual risk to humans at the anticipated exposures. If a reliable human risk cannot be obtained, then a risk relative to other important substances should be estimated. A conclusion that there is a significant risk leads to the third level of consideration.

Management must then consider the risk estimate in light of all other social factors, the costs of the regulation, the benefits of the candidate, and all other consequences of the decision to regulate or not regulate. One major factor for consideration is the proportion of resources of the Agency and of the nation which should be allotted to this problem; how great the danger is in comparison to other perceived dangers. Thus, the same concept of priority assignment which assisted in choosing which potential candidates to study will be helpful also in choosing which to regulate after an appropriate screening process.

Consequences of the Failure to Establish Priorities

It appears that much of the congestion within Agency decision channels has come from an excess of possible candidates at all levels, with no clear guidance mechanism to assist in an orderly categorization. In some instances this has led to an effort to control simultaneously not only all pesticides, as the National Academy of Sciences (NAS) study discusses, but also all potential water pollutants [18] or all suspect carcinogens, [4,6] or all volatile organic substances, [19] without adequate determination of the need for regulation of the individual members of these classes. Strong opposition to this excessively broad approach has delayed consideration of any single substances, because Agency resources were absorbed in defending the original approach rather than in developing the required data bases. Thus, the need for a method to set priorities is clear, both in intramural programs and on a national basis.

Other Suggestions for Establishing Priorities

Few writers have addressed the question of priority setting, seeming to prefer instead to discuss the degree of control which is to be applied rather than the order in which it is applied. One reason for this may be due to the very great difference of perception which various persons have for different forms of risk. [20] If we are unable to agree on which things are risky, we are not likely to agree on how

to abate the risks, or on when the risk has been reduced to a satisfactory level. Thus, activist groups such as the Environmental Defense Fund [21] accepts nothing less than a drive toward zero emissions and zero risk from whatever substance is in the process of being regulated. The President's Commission for a National Agenda for the Eighties expressed the opinion that environmental regulation should have a "high priority", but gave little direction except to express the feeling that marketplace forces, among other factors, should determine the weight of that priority. [22] Sir Richard Doll recently restated his belief that epidemiology is a powerful tool for identifying areas that require attention. [23] Useful efforts have been made in this direction by workers at the National Institute of Health, [24] Higginson, [25] and many others. Crouch and Wilson have proposed a system which goes beyond the NRC scope of pesticides, and which they say can be used to estimate the human risk of any suspect carcinogen. [26] A risk estimator is developed from the potency of the substance and the expected dose, and used to establish priorities. The method depends heavily on a number of assumptions as to the shape of the dose response curves and interspecies equalities, and is subject to other criticism such as ultraconservatism, [27] but may offer some assistance at making a first broad sweep at a large population of candidates. All of these suggestions have been general in nature, and none is of great assistance to a particular regulatory problem.

One of the few proposals for assigning priorities which has been developed in enough detail to be useful to the regulators is that by Blair, who has suggested [28] that the elephantine mass of potential candidates be digested one bite at a time. His proposal makes use of some of the steps already tried by various groups, but sets them in a coherent policy that leads to a useful final product. The major steps in his proposal are as follows:

1. Determine the universe of interest. For Blair this was the testing needs of the substances in the TSCA inventory, and was the class of pesticides in the NAS study.

2. Choose the relevant components of that universe. For the TSCA list, he proposed starting with the largest volume substances, plus those chosen by an expert panel from the remainder because of some specific reason for concern. NAS suggests usage as the criterion.

3. Separate those on which adequate data are available. This would be primarily those which have been regulated recently, or which have been in widespread use long enough to demonstrate relative safety.

4. Summarize the available information on the remaining substances. He suggested a scoring system similar to that now used by the ITC. [1] NAS proposed a potency index.

5. Establish an exposure score. Both environmental and occupational exposures would be rated by several factors. The NAS grouped these together in one usage index.

6. Determine critical missing data on those substances for which steps 4 and 5 were incomplete.

7. Refine the scoring as the data base becomes more complete, to give a final ordering of the degree of concern for the group. The scores of each step can be combined into a weighed composite final value.

It may well become apparent during this effort that some substances provide a high degree of concern early in the process, and should be singled out for more detailed study, while others may be eliminated. Many of the substances, however, will go through the entire process, and will form a potential candidate pool. The list will be ranked in order of decreasing concern from those candidates which warrant immediate consideration to those for which the risk is trivial or non-existent. It will be necessary at this stage for the Agency to assess the estimated relative risks in this ranking in comparison to the risks of ordinary life, and in view of the resources of the Agency. This will allow the selection of the most pressing candidates for further immediate consideration for regulation. A factor which should be included in this consideration is the ability of the Agency to obtain meaningful abatement of risk under its statutory authority.

Squire recently has proposed [29, 30] a method for ranking the potential concern for human risk from animal carcinogen test data which would be useful at this last step. This method weighs the scientific data for six factors and assigns the resulting scores to five classes which carry a graduated urgency for regulation. He deliberately omits any consideration of human data until this ranking step is complete, and thus furnishes another means of establishing the priority by which evaluation proceeds on an orderly step-by-step basis. Those compounds which yield the highest priority by his process would be the first to be considered at the next step by the incorporation of any available human or pharmacokinetic data. This suggestion assists the regulatory agencies in selecting the most cost-effective candidates for final recommendation to agency management.

A decision tree is a convenient device for organizing the available information for evaluation. The Food Safety Council [31],

and Campbell [32] and Park and Snee [33] have illustrated the use of this feature in recent papers. This device provides a useful means of displaying the many factors which should be considered in the evaluation of a substance, and for determining whether these data are available to the regulator. Campbell gives several examples of application to food additives which lead to reasonable decision on the degree of regulation which may be needed. He also illustrates how it can be used to conclude that added dietary protein, which can be termed a carcinogen under a strict interpretation of the Delaney philosophy, does not require regulation.

Application of sound scientific criteria to each substance during the evaluation process by such a method will help reduce the final candidate list to manageable size. Some of the methods used currently by regulators simply serve to carry a list of missing data down to the bottom line without adequate consideration of whether the unanswered questions actually are relevant.

The final package for the regulator in a particular agency will consist of a relatively small group of substances on which all of the available scientific data have been gathered and evaluated by independent experts, presented in a manner which will permit an ordering of the risks presented by each substance under the circumstances relevant to that agency, and including a summary of the actions being taken by other agencies.

National Priorities

Differing agencies will work on different universes of substances, but there will be overlaps among these groups. Thus, there should be constant coordination and cooperation among the agencies, both in data acquisition and regulator evaluation. The end result will be a relatively small and workable list of substances which will guide the agencies in their actions.

Various agencies and offices may use different weighing factors in assigning the final score. OSHA will be more concerned about the occupational exposure, EPA will be more concerned for the environmental exposure, and FDA the intake in foods.

Each agency should reevaluate the final score of a substance after another agency has taken regulatory action on it. Often the relative score will be changed substantially because of such action, and the agencies will feel less pressure to regulate a material simply because the other agency has done so. In fact, it may well be that because one agency has acted, the other agencies can direct their attention to matters of higher priority.

The final cumulative score will be valuable not only for establishing priorities within the agencies, but also for determining national priorities, both for immediate action, and for the allocation

of resources by Congress. If it should develop that the majority of the top scores were because of great environmental exposure, then the EPA would receive relatively larger appropriates than, say, OSHA.

The application of such a process for risk scoring will be of major assistance in developing a coherent national policy that will assure the most effective allocation of resources. Conscientious regulators which will do more good than harm. The use of such a national priority list can help assure that unnecessary effort is not being expended in relatively unproductive areas, or at the expense of a more critical need. We have no good way of establishing national scientific priorities at this time, [34] nor even for measuring the effectiveness of our regulatory efforts on a national basis. We must develop a method for establishing a sound scientific basis for setting these priorities and measuring the progress toward our goals.

Various modifications of the procedures suggested by the NRC and by Blair can be applied as appropriate, and the procedures undoubtedly will be modified as experience is gained in their use. It does seem important that some such procedure be applied on a national basis. Congress, the regulatory agencies, and society as a whole urgently needs guidance such as this process can provide in order to evaluate and direct our efforts in the protection of human health and the environment.

The increasing awareness that our resources are limited, on even a national scale, and that our past efforts have not been as productive or efficient as we might have wished, leads us to the conclusion that when regulatory action is taken it should be on the basis of the best available information in order to be cost-effective. To do otherwise will not only waste our resources on the regulation of politically important but toxicologically unimportant substances while more serious hazards may be ignored, it will discourage the development of the very data which we require for effective priority-setting. [35]

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Fifth Circuit Court of Appeals Decision On Consumer Product Safety Commission (CPSC) Urea Formaldehyde Foam Insulation (UFFI)

Introduction

As indicated in the editorial of this issue of the *Toxic Substances Journal*, Chief Judge Clark of the Fifth Circuit Court of Appeals in an April 7, 1983 decision has vacated the CPSC ban on UFFI.

Because this is an exceedingly important decision we have decided, with the kind permission of West Publishing Co., to reproduce the entire decision as a convenience for our readers since we know that this is an extremely imporant and potentially far reaching decision.

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Plastics Engineering*

Dr. James F. Carley, Engineering Editor

Dustless PVC eases processing

By Robert S. Holdsworth,† W. Mayo Smith,† and John T. Barr†

A new family of suspension-polymerized polyvinyl chloride resins is characterized by unusually large and uniform spherical particles (diam. = 0.2 to 0.6 mm.) and by its freedom from dust. Plasticizer absorption and flow properties of dry blends are excellent, as is general processibility. Electrical, physical, and visual properties are at least as good as those of established resins. To make dry blends, the new polymers should be mixed with plasticizer while cold, *then* warmed, reversing the traditional procedure. Four grades in different molecular-weight classes make possible a balance between certain physical and processing characteristics. These resins are processed in conventional equipment.

A newly developed process for the polymerization of vinyl chloride yields large, uniform polymer particles that are completely free of dust. The appearance of these particles suggested the name PVC Pearls.[1] Four grades are commercially available: Types 2250, 2225, 2200 and 2185, representing high, medium, low, and very low molecular weight respectively.

Vinyl chloride is usually polymerized as either an emulsion or a suspension in water. In emulsion polymerization, relatively large amounts of surface-active agents and catalysts are used. The resulting emulsion is then spray-dried or flocculated and very fine polymer particles are obtained. Most of the polymerization additives remain occluded to the polymer. The presence of these residual catalyst fragments and surfactants in the finished polymer is not always deleterious. However, in applications which require superior color, clarity, heat resistance, and electrical properties these added materials cannot be tolerated.

Most suspension polymerization formulations yield resins which contain minimum amounts of additives. In this process the amount of surface-active agents is very low, and the resulting polymeric product is obtained as a suspension which is separated from the water by filtration or centrifugation. Suspension polymer usually has a broad particle size distribution, ranging from dust-like particles of only a few microns to large particles of several hundred microns. However, since there is little extraneous matter present, the color, clarity, heat resistance, and electrical properties are good.

In the production of polyvinyl chloride (PVC) by the suspension process, an attempt is frequently made to produce a small particle size because this usually gives the best processing and physical properties. However, this

*Reg. U. S. Pat. Off.

The original version of this article was presented at the 14th Antec of the Society of Plastics Engineers, Detroit, Jan. 1958.

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[1]PVC Pearls is a trademark of Escambia Chemical Corp.

Fig. 1: Photomicrographs (40X) of PVC Pearls (left) and commercial PVC resin (right) before compounding. Differences in shape and size distribution probably account for good processibility of Pearls

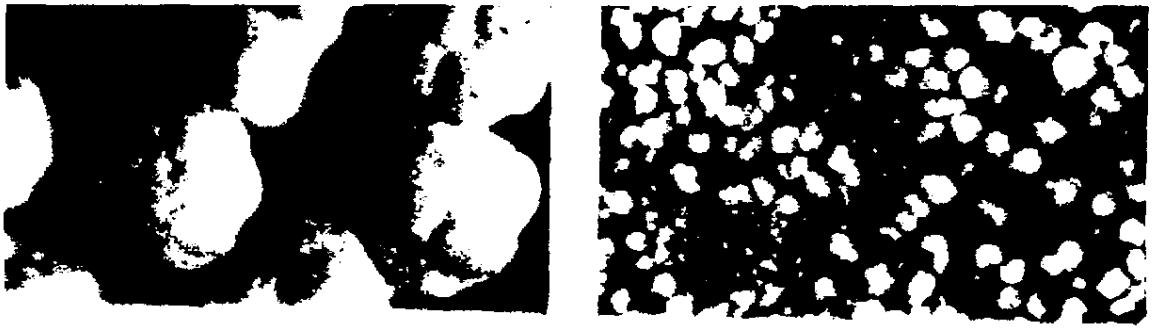


Table I: Particle size: PVC Pearls and conventional vinyl resins

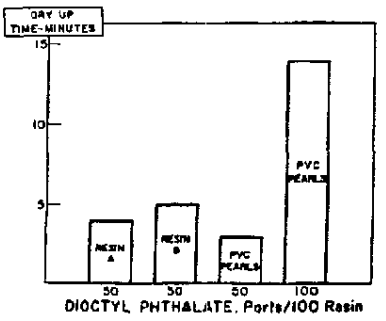
Screen analysis % retained on	*PVC Pearls Type 2250*	*Resin A*	*Resin B*
20 mesh screen	0	0	0
40 mesh screen	21	0	1
80 mesh screen	79	26	3
100 mesh screen	0	54	20
140 mesh screen	0	17	47
200 mesh screen	0	3	20
Through 200 mesh	0	0	9
Bulk density, lb./cu. ft.	30.2	30.6	33.2
Relative viscosity (1% in cyclohexanone @ 25° C.)	2.45	2.37	2.44

small particle size causes objectionable dusting during handling and results in weight losses.

PVC Pearls are made by a radically different suspension polymerization that yields large particles. Partly because of this, the Pearls have been found to process more easily than the other suspension resins. The physical properties of finished Pearl compounds are equal or superior to those of conventional resins. Dusting is eliminated while bulk density remains virtually the same as that of conventional resins. Screen analyses of a PVC Pearl polymer and two widely accepted commercial PVC resins which were probably prepared by suspension are given in Table I, above.

The Pearl particles appear to the eye to be smooth, uniform spheres, but photomicrographs (Fig. 1, p. 131) show that the PVC Pearls actually have a rough, pitted surface. Thus, one would expect the effective surface area to be large, because of the microscopic irregularity of the particles. This expectation is confirmed by absorption studies.

Fig. 2: Time required to make dry blends from different PVC resins. A and B could not take up 100 parts of DOP without getting sticky



Plasticizer absorption

A great deal of the PVC resin produced is used in applications which require a flexible material. This flexibility is achieved by the incorporation of suitable plasticizers. The resin and plasticizer may be pre-blended at room temperature and the mixture warmed to a point below the fusion temperature of the resin to speed distribution of the plasticizer into the resin particles. The result is a blend that feels dry to the touch.

An acceptable PVC resin should absorb the required amount of plasticizer and should yield a dry blend on warming. The blend should be dry enough to flow through lines or be blown through a conveying system without caking or otherwise interfering with processing.

The heating time required to produce resin-plasticizer dry blends and the flow properties of these blends were studied. The resin and plasticizer were blended in a Hobart Mixer (model N-50). A steam jacket was built onto the bowl of this mixer and the temperature of the bowl was held at 100° C. during the test. The mixer speed was 140 r.p.m. The dry-blend time is defined as the time required to produce a dry resin-plasticizer mixture while the bowl is held at this temperature.

A comparison of the dry-blend times of the PVC Pearl polymer with two commercial resins reported to have outstanding dry-blend qualities was made and is shown in Table II, below, and Fig. 2, left. The PVC Pearl resin is

Table II: Absorption of dioctyl phthalate plasticizer by PVC resins

Resin	*Parts DOP per hundred resin*	*Dry-up time*	*Dry blend flow rate*
		min.	*g./sec.*
PVC Pearls	Unplasticized		9.1
PVC Pearls	30	0	8.4
PVC Pearls	50	3	6.2
PVC Pearls	70	5	4.5
PVC Pearls	90	11	4.4
PVC Pearls	100	14	4.0
PVC Pearls	120	85	3.8
PVC Pearls	150	180	3.4
A	Unplasticized		7.7
A	30	1	6.7
A	50	4	3.2
A	70	5	2.9
A	90	15	2.3
A	100	>100	Will not flow
B	Unplasticized		5.0
B	30	5	Will not flow
B	50	5	Will not flow
B	100	>100	Will not flow

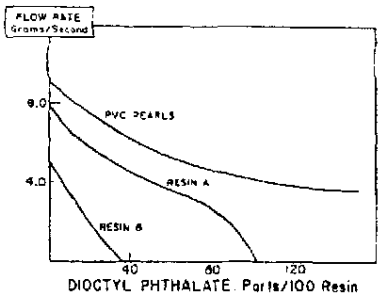


Fig. 3: Flow of resin particles through test funnel drops off as dioctyl phthalate (DOP) content rises

about equivalent to the best commercial resins in its ability to quickly absorb 50 parts of dioctyl phthalate (DOP) per 100 parts of polymer. However, only the Pearl polymer would absorb 100 parts of DOP and yield a dry blend in this test. The Pearls are, therefore, strongly recommended where high plasticizer levels are used.

For maximum processing economy, a resin should not only have good plasticizer absorption but the resulting dry blends must flow readily. The flow times of resin-plasticizer blends through a 60° stainless steel funnel having a ½-in. opening were measured. In Fig. 3, above, these flow rates of DOP-Pearl dry blends are shown to be high, even at extremely high plasticizer levels. One of the conventional resins is seen to flow fairly well at moderate DOP levels, but the other did not flow at all, even at the low DOP level. Only the Pearl polymer produces dry blends with high, consistent flow rates over a wide range of DOP content.

Polymeric plasticizers are frequently used in PVC compounding. Pearl resins are particularly recommended for applications in which appreciable quantities of these polymeric plasticizers are required. As shown in Table III, below, the polymer will absorb up to 100 parts of Paraplex G-50, a commercial polyester plasticizer with a molecular weight of 2200. These data also show that the flow of the dry blend made from this polymeric plasticizer and the Pearl resin was superior to that of the blend made with conventional resin. The Pearl polymer imparts excellent flow even when 80 parts of this polyester plasticizer are used. Dry blends with conventional resins fail to flow at these plasticizer levels.

It is interesting to note that dry blends made with PVC Pearls and the polyester plasticizer flow better at low plasticizer levels than those made with DOP. However, considerably more DOP than Paraplex G-50 can be absorbed without complete loss of particle flowability.

The large uniform particle size is probably responsible for these excellent flow properties of the Pearls, since there is no fine ma-

Table III: Absorption of polyester plasticizer by PVC resins

Resin	*Parts Paraplex G-50 per hundred resin*	*Dry-up time*	*Dry blend flow rate*
		min.	*g./sec.*
PVC Pearls	Unplasticized		9.1
PVC Pearls	30	1	10.0
PVC Pearls	50	5	10.0
PVC Pearls	70	40	10.0
PVC Pearls	100	60	Will not flow
A	Unplasticized		7.7
A	30	1	7.7
A	50	6	7.7
A	70	>60	Will not flow

Table IV: Extrusion of PVC Pearls

Pearl resin	*2250*	*2225*	*2200*	*2185*
Relative viscosity (1% in cyclohexanone @ 25° C.)	2.45	2.25	2.03	1.85
Specific viscosity ASTM D 1243-54	0.42	0.37	0.31	0.27
Extrusion rates, p.p.h.				
Screw speed = 8 r.p.m.	16	20	24	34
Screw speed = 11 r.p.m.	24	27	38	46
Screw speed = 14 r.p.m.	31	38	48	58
Screw speed = 16 r.p.m.	39	44	52	68
Screw speed = 18 r.p.m.	44	51	65	78

Extruder temperatures, °F.	
Zone 1	260
Zone 2	320
Zone 3	390
Zone 4	410
Gate	385
Head	420
Die	385

Compound	
Pearl resin	100.0
Dioctyl phthalate	45.0
Epoxy plasticizer	5.0
Cadmium stabilizer	3.0
Stearic acid	0.5

Fig. 4: In extrusion of flat strip from plasticized PVC Pearls, output falls as molecular weight rises

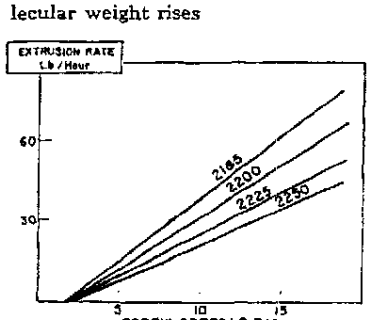


Table V: Physical properties of PVC Pearls

Type	2250	2225	2200	2185
Relative viscosity (1% in cyclohexanone @ 25° C.)	2.45	2.25	2.03	1.85
Specific viscosity ASTM D 1243-54	0.42	0.37	0.31	0.27
Tensile, p.s.i.	2900	2850	2650	2400
100% modulus, p.s.i.	2000	2000	1900	1850
Elongation, %	315	290	280	250
Hardness, shore A	89	90	87	86
Tabor abrasion loss 2000 cycles, g.	0.130	0.145	0.150	0.170
Heat resistance min. to black @ 190° C.	90	75	60	45

Compound	
Resin	100.0
Dioctyl phthalate	42.5
Barium-cadmium stabilizer	2.5
Epoxy stabilizer	1.0
Stearic acid	0.5

terial to pack between the large particles and especially since there is less contact surface between particles.

Extrusion of dry blends

PVC Pearl compounds may be extruded with standard plastics extruders, without prior milling or intensive mixing.

It is well known that variations of the blending and extrusion conditions can strongly influence the quality of PVC products. A few of the most important considerations are described in the material below.

As already noted, the Pearls absorb plasticizer readily, and if proper precautions are not taken when small to moderate amounts of plasticizer are used, uneven distribution may result. Dry blends prepared with conventional PVC resins are frequently made by heating the resin and plasticizer before mixing. With the Pearl polymers, this technique tends to overplasticize the particles which are wet first and leave the remaining Pearl particles with practically little or no plasticizer.

Studies in a 1.8-cu.-ft. ribbon blender have shown that more uniform plasticizer distribution is obtained by first mixing the Pearls and plasticizers at room temperature, and then by warming them sufficiently to obtain a dry blend.

Dry blends prepared by both of these techniques were extruded. The dry blend prepared by mixing preheated materials yielded a strip containing hard, unplasticized particles, while the cold-mixed, post-heated dry blend yielded a strip free of these imperfections. In later studies it was found that Pearl dry blends extrude best under conditions which resemble those used for the extrusion of granulated compounds rather than conditions usually required for fine-powder dry blends. Extrusion rates up to 25% above those for normal dry blends have been obtained in production runs with the proper extruder conditions.

Table IV, p. 133, lists the conditions of some extrusion-rate experiments, results of which are shown in Fig. 4, p. 133. The dry blends were extruded as strips 1¼ in. wide by 1/16 in. thick from a 2.5-in. NRM extruder having a L/D of 20. Grades 2250, 2225, 2200, and 2185 were run. The plots of extrusion rate versus screw speed are best represented by straight lines for these resins and conditions. There was a significant drop in output as molecular weight rose. The resin having the highest molecular weight gave the slowest extrusion rate at a given screw speed. The color and clarity of the extruded tapes were good.

Calendering

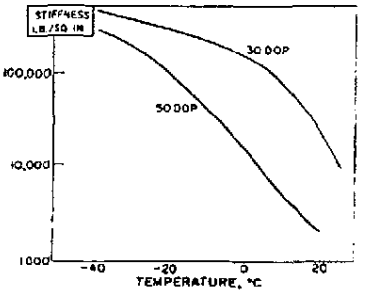
PVC Pearl polymers were compounded in an internal mixer and calendered into film using a four-roll, inverted-L, 8- by 16-in. calender. This film was free of gel particles or "fisheyes" and again exhibited unusually good color and clarity. It was readily heat sealed with standard radio-frequency heat-sealing equipment, giving seals that were stronger than the film.

Physical properties

Pearl polymers of the four different molecular weights listed in the first paragraph of this article were compounded with 42.5 parts of DOP and stabilized with a barium-cadmium-epoxy system. The physical properties of these compounds are shown in Table V, above. As expected, the high-molecular-weight resin had the maximum tensile properties, abrasion resistance, and heat resistance. These properties fell off as the molecular weight of the resin was reduced. In choosing a resin for a given use, one must remember that while better physical properties are obtained at high molecular weights, the lower-molecular-weight resins have better processing characteristics. The availability of four molecular-weight grades enables the user to select the resin offering best balance of physical properties and processing economics.

Torsional stiffness of these compounds was measured over a

Fig. 5: Molecular weight had no effect on stiffness-vs.-temperature characteristic of Pearl resins, though DOP content was important



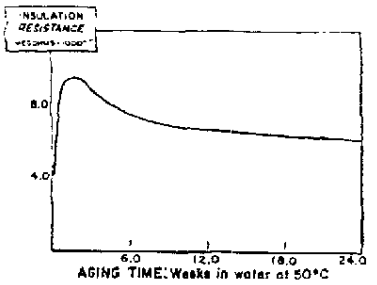


Fig. 6: After about six weeks, insulation resistance of Pearl resin wire-covering seems to stabilize at about 65 times U/L minimum requirements

Table VI: PVC electrical insulation

PVC Pearls	100.0
DOP, electrical grade	52.0
Basic lead carbonate	10.0
Clay, pigment 33	7.0
Lead stearate	0.5
Compound extruded on #14 copper wire	
Insulation resistance = 6.5 megohms —1000 ft.	
Aged 24 weeks in water @ 50° C.	

range of temperature, using the test developed by Clash and Berg (ASTM D 1043-51), with the results shown in Fig. 5, p. 136. Each resin was run at two plasticizer levels—30 and 50 parts of DOP. At each level of plasticizer content, a single curve represented the behavior of all four resins.

Thus, while the plasticizer level has a significant effect, the molecular weight of the resin, in the range that is reported here, does not materially affect the torsional stiffness.

Electrical insulation resistance

PVC resin is widely used as electrical insulation on wire. Good electrical insulation properties, wide color range, ease of production, and low cost are several of the factors which make vinyls attractive.

The suitability of a given PVC resin for electrical applications is best determined by preparing a compound and actually using it to insulate wire. The insulation resistance is measured while the wire is immersed in water. It is desirable to test over an extended period of time to account for such factors as aging, shrinkage, leaching out of plasticizer, and water absorption.

The high molecular-weight Pearl polymer was compounded in an electrical stock as shown in Table VI, left, and this compound was extruded on #14 copper wire at about 300 ft./min. in a thickness of 1/32 inch.

The wire was immersed in water at 50° C., and the insulation resistance was measured over a period of 24 weeks. The results of this test are shown in Fig. 6, left. The insulation resistance of Pearl compound levels off after about six weeks, indicating that the compound has good aging qualities. The equilibrium insulation resistance of 6.5 megohm-kilo-feet is considerably above the Underwriters' Laboratories requirements of 0.1 megohm-kilo-feet.

The Pearl resin was evaluated by a large insulated wire manufacturer. Aging studies showed that the insulation compound retained 94% of its original elongation after aging seven days at 113° C., while the retention of elongation of a good electrical grade commercial polyvinyl chloride resin was only 88% in the same test.

The acceptable insulating properties of compounds based on the Pearl polymer, together with the ease of extrusion directly from dry blends, suggest the use of this resin for electrical applications, especially for jacketing outdoor wiring and for building wire.

Rigid compounds

The PVC Pearl polymers are particularly well suited for rigid applications. A low-molecular-weight polymer is usually preferred, since little or no plasticizer can be used and optimum processing properties are required. The low-molecular-weight polymer, Type 2200, was stabilized with 3% of dibutyl tin mercaptide and milled on a 16-in., differential-speed mill at 177° C. stock temperature. The compound was found to band quickly and a smooth, rolling bank was obtained. The heat stability of the compound was outstanding as compared to that of commercial polymers (see Table VII, below). The physical properties were determined and all the resins studied were found to be equivalent to those of competitive resins of similar molecular weights.

The low-molecular-weight PVC Pearls are recommended for rigid applications in which normal heat distortion temperature and impact strength are required with low-temperature processing, good color, clarity, and heat resistance.

Acknowledgments

The authors are indebted to many of their fellow workers who helped produce the information here: A. Di Nardo, J. F. Gabbett, V. R. Pallas, J. R. Grant, N. T. Flathers, R. E. Johnson.—END

Table VII: Properties of PVC rigid compounds

	PVC Pearls Type 2200	*Resin C*	*Resin D*
Relative viscosity (1% in cyclohexanone @ 25° C.)	2.03	2.14	1.84
Milled @ 177° C. time to discolor, min.	90	40	30
Heat distortion temperature, °C. fiber stress of 66 p.s.i.	80	80	——
Heat distortion temperature, °C. fiber stress of 264 p.s.i.	75	75	74
Izod impact, ft.-lb./in. of notch	0.82	0.88	0.70

Compound	
Resin	100.0
Dibutyl tin mercaptide	3.0

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The Use of Risk Assessment in Regulatory Decision Making: Time for a Review[1]

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The Interagency Regulatory Liaison Group issued a draft report entitled "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks" in 1979 for public comment. This draft has been implemented as policy by several major federal regulatory agencies stultifying further progress in developing adequate scientific analysis of the data base for regulating carcinogens. Excessive reliance on value judgments by Agency staff has produced a drive toward zero risk and perfect safety which has obscured from the regulatory decision maker the true extent of the risk which may be present. This paper presents the need for separation of the scientific and political steps in risk analysis, and provides suggestions for obtaining proper validation and interpretation of scientific data. The need for clear presentation to the public of the assumptions used in risk analyses is emphasized, as is the necessity for greater participation by the scientific community in this process. To accomplish these objectives the IRLG report should be reevaluated and revised extensively to prepare a sound scientific foundation for the use by regulatory agencies.

INTRODUCTION

The Interagency Regulatory Liaison Group (IRLG) was formed by the heads of the Consumer Product Safety Commission (CPSC), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA) in 1977 to increase the cooperation between these agencies in their efforts to regulate toxic and hazardous substances, and to improve the effectiveness of their programs (1). The Food Safety and Quality Service (FSQS) joined the group in January 1979 (2). One result of this cooperative effort was the simultaneous publication (3) in July 1979 in the *Journal of the National Cancer Institute* and the *Federal Register* of a draft report entitled "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risk: Request for Comment on Report." The *Federal Register* notice stated that

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"(a)fter reviewing comments received, the four agencies anticipate publishing a statement giving notice of whatever revisions to the document are appropriate, if any." Unfortunately, the "phasing out" of the working group on risk assessment was announced by IRLG Chairman Allen Heim at the end of May 1979. No provision was made for the evaluation of public comment on the IRLG Report. Chairman Heim stated that risk assessment would be undertaken directly by senior officials from the five participating agencies (4). Thus, other than a discussion of, and an expansion on, some of the philosophies contained in this document by one of the participants in its preparation (5, 6) no further action has been taken by the IRLG on this document since its original publication. The FSQS announced recently (7) that it was seeking a contractor to review the comments which have been received, but the proposal request now has been withdrawn.

The Report discussed the evaluation and application of evidence for carcinogenicity of substances, and described methodologies for estimation of risk to humans from that evidence. Even while public comments were being received, the Report was adopted (8) by the Regulatory Council, a larger group of regulatory agencies, and the policy position was presented again for comment and possible revision. That had the effect of broadening the influence of the draft Report greatly among government agencies. The rationalization of current Agency policies on a multi-agency basis had the effect of suppressing individual Agency initiatives in scientific evaluation and risk assessment. The policies announced as drafts became in practice the governing force in Agency decision making.

Application of the policy espoused in the IRLG document since its publication has had the appearance of unevenness. Although its representatives sat on the drafting committee, OSHA did not claim authorship of the IRLG draft paper in its publication in the *Federal Register*, because of possible legal implications for the generic cancer regulation which then was in development. OSHA, however, was cited as an author when the IRLG Report was published in the *Journal of the National Cancer Institute* (3). While OSHA has not officially embraced the policy of the IRLG Report, the OSHA generic cancer regulation reflected the major science policy rationalizations in the IRLG Report (13). OSHA, however, imposed more administrative political constraints on scientific risk evaluation than did the IRLG Report. CPSC (9) and the EPA (10) have stated publicly that they rely on the policy for guidance for their regulatory decisions. It also has received considerable publicity elsewhere (11) in the governmental circles, and thus must be looked on as an influential document.

The American Industrial Health Council (AIHC), along with many others, submitted extensive comments to both IRLG and the Regulatory Council in 1979, suggesting that numerous revisions were necessary to assure that the best current science was utilized in the scientific evaluation of all the available evidence, and that an independent science panel would be the most effective method to assure this. Vice President Bush, as chairman of the Task Force on Regulatory Relief, has asked that regulations or policies which result in overregulation be identified for reevaluation. In a letter to the Task Force, AIHC has called for a review of the policy embodied in the IRLG Report (12). The IRLG Report must be revised before it is suitable for adoption as an official policy. It is essential that there be a coherent federal policy for the proper utilization of science in regulatory decision making. Revision, therefore, should consider both the comments which were sub-

mitted in 1979 and the comments by the independent scientific community reflecting the advances in this area which have occurred since that time.

The remainder of this discussion will deal with how best to assure that these goals are achieved, and is based on the comments made to IRLG and the Regulatory Council by the AIHC in 1979, and on recent developments.

THE CURRENT STATUS OF RISK ASSESSMENT IN REGULATORY AGENCIES

Interest in the use of risk assessment, both qualitative and quantitative, in regulatory decision-making processes has increased rapidly in recent years. It is an underlying feature in the nuclear energy field. The Food and Drug Administration (FDA) is considering (14) a procedure for allowing trivial residual concentration of potentially harmful substances in foods and drugs. The Consumer Product Safety Commission (CPSC) has used various methodologies in its decisions and published recently (9) a description of how it "uses quantified cost–benefit analyses as one of many tools in regulatory decision-making." The Occupational Safety and Health Administration (OSHA) promulgated (13) a policy on workplace exposure to potential carcinogens which deliberately excluded the use of quantitative risk assessment from its consideration of the degree of abatement to be required, but recently revised (15) its policy to include a risk assessment as the result of a Supreme Court decision on its benzene standard holding that OSHA must make a threshold finding of "significant" risk at present conditions as a prerequisite to regulatory action on a substance. Additional amendments which would have established a policy to "eliminate significant risk" have been withdrawn (16) for reconsideration of the entire policy. Thus, although no regulations reflecting this reconsideration have yet been published, it seems clear that some effort at quantitation will be made by OSHA in its rule making on carcinogens.

The Environmental Protection Agency (EPA) has published (17) its policy on risk assessment procedures, and has used that methodology to estimate risks at various levels of environmental exposure for several substances (18–20). Requirements for a cost–benefit analysis of major rules by executive branch agencies were imposed by Executive Order 12291 (21), which calls for the potential benefits and the potential costs to be described for the proposed rule and for alternative approaches. Bills calling for similar requirements for all federal agencies have been introduced into both houses of Congress (22, 23). These actions will place much greater demands on the agencies to develop methods for the risk assessments which will be necessary before appropriate cost–benefit analyses can be made.

A general theme which has run through most of the regulatory process up to this time is based on the conclusion that currently it is impossible to demonstrate the existence of a threshold or no-effect level of exposure to chronic health hazards so it must be assumed that there is some risk at any exposure (13, 17). Both OSHA and EPA have gone further to require in most cases, at least before the recent Supreme Court *Benzene* decision, that all exposures must then be reduced at least to the lowest limit of technical feasibility (10, 13). Further, they base their quantitative risk assessments on what they describe as "prudent and conservative assumptions" (15, 17). The usual route for arriving at the final estimate is to employ

a no-threshold linear-through-zero extrapolation (or an extrapolation model which has the same effect at low doses) from an animal bioassay on the most sensitive species, and taking the upper 95% confidence limit of the result, which is then extrapolated as the basis for evaluating the risks of human exposure (24). Additional adjustments sometimes are made for an assumed greater responsiveness in humans because of the larger surface area or other physical differences, which results usually in lower calculated allowable exposures (25).

This "conservative" model assumes that all possible combinations of dose and length of exposure are equivalent when calculated as total dose. That oversimplification is not justified for all types of carcinogens, because it assumes that metabolism and repair mechanisms are not affected by dose levels, as will be discussed later. It also assumes that humans have the same sensitivity as the most sensitive test species used, another unwarranted conclusion.

There is some indication that the agencies realize the excessive conservatism of this approach. For example, the EPA recently stated that when oncogenic risks to workers exposed to arsenic were "estimated by standard Agency techniques—the Agency believes that the model tends to overstate the actual risk in this case because of adjustments and assumptions made to handle uncertainty in a conservative manner" (26). The Agency expressed the same "caveats" for the other substances included in this rule making.

A much sounder expression of the regulatory significance of the risk overstatement by "conservatism" is set out in FDA's reasons for permitting the continued use of lead in hair dyes. The FDA replied (27) to those who expressed concern that the published risk assessment would predict the death of one person per million users by stating that these were "worst case estimates." It went on to say that "(u)pper limit estimates by risk using 'worst case' assumptions cannot be used to predict with mathematical precision what will actually occur. Yet, because risk estimates take into account the risk resulting from incomplete information, extreme assumptions of overuse, abuse, and overapplications, etc., (hence, 'worst case estimates'), are factored in to reach a conclusion with reasonable certainty of what will not occur."

One cause for confusion in the minds of the public has been the use by the agencies of these "conservative" risk calculations in rule making. The result is that estimates often are presented as a single figure with no discussion of the conservatism which biased the calculations, the uncertainties involved, or of the probable limits of the calculated figure. Despite the development of many possible mathematical models for use in risk assessment, no coordinated effort has been disclosed by regulatory bodies in which an attempt was made to test or apply these models in situations where they could be evaluated properly as to their biological validity. This has led to an unevaluated drift in the direction of "prudent" conservatism, which has been accelerated by the application of these conservative assumptions early in the scientific and mathematical evaluations of experimental results. The outcome has been an estimate in which the final decision maker cannot differentiate between facts and assumptions in the scientific evaluations. When the public has understood this situation, for example, in the case of saccharin, there has developed a significant lack of confidence in the entire risk assessment process. A critical discussion of the various mathematical models available today is beyond the scope of this paper. The Food Safety Council has compared four of the most frequently

used models for several substances and provided a helpful discussion of the probable applicability and shortcomings of each (28). Interested persons are referred to that report for more details. These models can be useful in estimating human risk under specified conditions when they are utilized in light of their biological significance. The mathematical expression cannot necessarily be used to predict the mechanism by which a substance acts as a carcinogen, but the model must at least be compatible with that mechanism.

In the midst of the difficulties described above the IRLG began to develop a summary of recommended practices for use by regulatory agencies in the identification of potential carcinogens and the estimation of risks from exposure to these substances. The draft report which resulted (3) does contain discussion of the criteria for some facets of the evaluation program, but it is incomplete, and so biased against distinguishing between trivial and significant risks that it must be revised extensively to make it compatible with the state of the art in this field as it is now developing.

RISK CONTROL

Effective control of risk from potential health hazards consists of three phases. The first is identification of the hazard, sometimes called qualitative risk assessment. The second is estimation of the risk for humans under some expected route of exposure, or quantitative risk assessment. The third is risk management, which involves the decisions concerning the extent to which the perceived risk should be abated and the methods to be used in doing so.

The first two of these phases are, or should be, scientific decisions involving evaluation of the relevance and validity of data and methodologies, including mathematical modeling, for quantifying the risk to man. The last phase is a socioeconomic decision which generally requires utilization of concepts outside the scientific arena. It is a political decision, in the broader and nonpejorative sense of that term. This decision is one which must be made by the management of a company which faces a potential hazard to its workers, customers, or neighbors, or by the administrative level in regulatory agencies, on whom society has placed the responsibility for protecting the public (29, 30).

A major fault in the current regulatory process has been the intermingling of these three phases of risk identification and management. The final decision maker is faced with an evaluation labeled scientific which often is so clouded by a mixture of science and politics that the administrator is unable to exercise his assigned responsibilities of deciding whether the risk is trivial and should be forgotten or whether the risk is significant and should be regulated. For example, members of the EPA scientific staff have stated that they "lean over in the direction of giving weight to evidence of carcinogenicity" (31) in a deliberate effort to influence the policymakers to regulate whenever there is any evidence, no matter how slight, of a possible chronic hazard. In face of such an evaluation the regulator is driven toward regulation because the evaluation deliberately disregarded the distinction between a trivial and significant risks. In that situation the regulator cannot make a rational identification of regulatory alternatives or a sound evaluation of these possible alternatives.

Qualitative Risk Assessment

Qualitative risk assessment, the recognition of a potential hazard, requires that some conclusion be drawn from existing data on the likelihood for risk to humans from exposure to a substance. Actual human experience often is lacking, or is too imprecise to allow a firm conclusion to be drawn from it. Therefore, there is a growing reliance on the results from tests on animals, usually rodents, or on bacteria or other lower species of life. The regulatory philosophy in the IRLG Report is that any positive indication of hazard from these tests must be taken as a signal for the need for regulation of human exposure. The very large number of substances in our industrial and social environment, the uncertainties related to human relevance, and the time and limited resources for testing on higher species all are cited as the reasons for immediate response to a positive signal, negative results from other tests or data notwithstanding. This is the first of several conservative assumptions which result in a drive toward zero risk and the impossible goal of perfect safety (32, 33).

Screening tests. The effect of the policy set forth in the IRLG Report is that tests designed as screening tests for use in the decision as to the need for further study have been converted instead into accepted bases for regulatory action. The National Cancer Institute often has stated that its standard bioassay test using the maximum tolerated dose and one other level is "meant to screen chemicals for cancer-causing potential, not to predict the frequency at which cancer will appear in human populations" (34). The EPA currently is evaluating the Phase I results of its GENE-TOX program for validation of the many short-term screening tests for mutagenicity and carcinogenicity (35). The general conclusion that can be drawn from the statements by both of these groups is that neither of these screening programs is appropriate for direct application to human exposures at this time. The preliminary data from bioassays and short-term tests should not be used except possibly in an initial screening program to compare potencies or determine priorities for further studies. Certainly, all tests must be validated before their results are used in any quantitative fashion.

Validity of data. Proper application of the results of either short-term tests or animal bioassays requires consideration of many factors, among them the quality of the test procedure used, its validity for the application under consideration, the ability to replicate the results in other species or other laboratories, the expected route of exposure, and, certainly, the biological significance of the results. Interspecies metabolic differences must be considered as well. The policy of the IRLG Report, as interpreted by the agencies, unfortunately leads to undue reliance on these preliminary data. EPA's Cancer Assessment Group uses both NCI bioassay results and short-term test results directly in its carcinogenic risk assessments, without proper regard for the factors listed above.

Negative results. Due weight must be given to negative results, including negative human epidemiology studies, which often can be used to establish upper bounds of potential risk, and thus to assist in the ordering of priorities of suspect substances to assure that those which pose the greatest potential risk receive attention first. Failure to accept valid negative results is another "conservative" push in the search for zero.

Synergism. Additive, or multiplicative, effects are recognized for cigarette smok-

ing and exposure to asbestos and alcohol, and perhaps radiation in miners. Other examples are not conclusive that the additive effect extends to all other combinations of biological insults. In fact, there are many examples where a substance exhibits a protective or inhibitory effect on tumor development, or on extending the life of the exposed groups (36, 37). Thus, there must be adequate consideration of the mechanism of the carcinogenic action in order to evaluate any possible synergistic effect.

Benign tumors. Still another conservative assumption is the determination that the induction or enhancement of benign tumors, or of types of tumors to which the test species has been bred to be particularly susceptible, is an indication of hazard in humans. There are sound pathological reasons why tumors are differentiated as benign or malignant (38).

Animal tests. It is recognized that random variations in colonies with a high spontaneous incidence of certain tumors make the recognition of significant responses very difficult. Genetic drift within colonies is another confounding factor, making the use of historical or external controls difficult (39). It is therefore necessary that careful scientific scrutiny be applied to any consideration of the relevance of animal data to human hazards.

Quantitative Risk Assessment

Quantitative risk assessment usually is an even more difficult task than the identification of potential hazard because of the problems in translating animal data into human risks. There is not, at this time, any appropriate general model for quantitative extrapolation between animals and humans (28, 38). In those few cases where extensive comparisons have been made of the mechanism of carcinogenesis in both groups, the available data suggest strongly that there are several classes of carcinogens, some of which may not have no-effect levels, and some of which may well have and thus will require different extrapolation models. It is becoming increasingly clear that not only is "cancer" a large family of diseases, containing a hundred or more specific types, but the causes of cancer also fall into several categories, which require different regulatory approaches that are based on different scientific descriptions of the underlying causal mechanism.

Some of the classes into which carcinogens are recognized (40) to fall include:

—complete, or direct acting carcinogens;

—procarcinogens, which require metabolic activation in the host;

—systemic carcinogens, which stimulate or suppress natural hormonal or immune systems and thus alter natural processes sufficiently to allow tumors to develop;

—bionutrients, which are themselves essential to life, but which in excess may be carcinogenic;

—cocarcinogens, which require the presence of other substances for action;

—promoters, which accelerate the activity of other types of carcinogens;

—solid-state carcinogens, which in the proper state of subdivision, produce tumors at the location in the host;

—physical agents, which damage cells and stimulate rapid proliferation of growth which may exceed the regulatory processes of the host;

—virus-induced carcinogenic response.

It is most improbable that all of these mechanisms can be described properly by the same mathematical model. It is equally improbable that none of them have some level below which the stimulus is insufficient to prevent detoxification or regulation by the host. For example, in the case of those procarcinogens which require metabolic activation, there are not only differing routes and rates of metabolism in various species at various dose levels, but there are competing deactivation and excretion processes. Similarly, for physical agents, there are recognized dosages below which the cell damage does not occur.

Choice of models. Often the mechanism by which a particular substance operates is unknown at the time of concern for its carcinogenicity is first raised. Even if adequate data are avialable to determine a dose–response curve which fits a certain model, there is no assurance that this model will predict the mechanism by which the substance acts in humans, and more detailed studies usually are necessary to determine the classification into which the substance falls. For the same reason, it is improper to assume for regulatory purposes that the linear-through-zero model is appropriate in all cases. It may well be a useful model for establishing priorities for further studies, but the results of such an exercise should not be used to prescribe control levels, or even to determine which substance from a list of candidates should be regulated. Careful scientific evaluation will show, we believe, that it is useful, at best, as a preliminary screening guide without biological validation for the substance under test. Until such time as we are able to specify one mathematical model as the appropriate for a particular substance of type of tumor, the preliminary risk estimates should be made with several models in an effort to determine which one best represents the facts for that particular case.

Time to tumor. Recent advances in computer technology have made it possible to perform much more detailed analyses of animal data. A Committee of the Society of Toxicology (SOT) undertook a detailed review of the enormous "ED_{01}" study of chemical carcinogenesis in mice (41) as induced by 2-acetylaminofluorene (AAF). The results were presented at the 1981 Annual Meeting of the SOT in San Diego on March 5 (42). A summary of the findings of the committee which was released at that time stated:

> The major implications of these conclusions are:
>
> (1) Our analysis of their data does not support their conclusion of a lack of a threshold effect. A linear interpretation is not supported by either the revised bladder data or, if an adjustment is made for time on study, by the original (and validated) liver data.
>
> (2) The ED_{01} study shows that a realistic risk assessment for AAF should include a component of time to have biological meaning. When this is done the tumor-free period as a function of dose has a slope that is indistinguishable from zero over a considerable region including the lowest dose used in ED_{01} study.
>
> The time to tumor data obtained from the ED_{01} study interjects a third dimension of overwhelming importance into the evaluation of carcinogen dose and tumor development relationships. Time is no longer a nuisance parameter that need merely be adjusted for, but rather time can be directly incorporated into the very definition of risk assessment. This leads to a new generation of risk assessment methodology that incorporates the dose, the response, and the time to tumor data.

The IRLG Report will continue, until it is properly reevaluated, to restrict scientific evaluation to the use of methods which were adopted in the past because

of conservative or nonscientific considerations. A reevaluation of the report should permit new concepts to be used as they become available. Some method or methods of extrapolation must be chosen for evaluation of risks beyond the available data range, but the choice of extrapolation model must be made only after careful consideration of all relevant biological factors. Many of these are the same factors which are considered for the qualitative estimation, but in addition, pharmacokinetics and the level, route, and extent of exposure are also important.

Potency. The potency of carcinogens is known to vary by many orders of magnitude in both test animals and humans, and evaluation of potential risk requires allowance for this factor. In particular, the question must be faced of when a risk becomes significant enough to warrant control beyond that available through current regulations. The scientist must assist the regulator in the efficient allocation of resources by providing information on relative risk comparisons with other potential candidates and the risks encountered in everyday life. Certainly, there are risks for which the perceived benefits are adequate for public acceptance, such as in the case of saccharin, and for which further control other than adequate warning is unnecessary.

Presentation of results. The numerical results of risk estimation should be presented as a most probable value under specified conditions of expected exposure, including both time and extent, and the range which this value may have under specified statistical limits. Both upper and lower confidence limits should be reported, as should all assumptions or value judgements which were used in reaching the final range. The regulator then has the necessary information evaluating the significance of the risk and for choosing the appropriate levels of controls and abatement methods. The Office of Science and Technology Policy has presented a detailed discussion of why this is a necessary and proper procedure in the regulatory process (43), emphasizing "the importance of well-organized scientific inquiry, objective review of evidence regarding carcinogenicity, and detailed characterization of potential risk to humans" as the essential preliminary step before regulatory decisions can be made.

Application of results. In making regulatory choices, the regulator can use risk assessment in various ways. One of these is, as mentioned above, comparative risk assessment, which can be a valuable tool for helping the public develop a proper perspective on a proposed rule. A comparison of the estimated risks from the substance under consideration with the other risks involved in everyday life, both voluntary or involuntary, will aid in evaluating both the need for a regulation and the degree of regulation which is necessary to control unreasonable risks.

Another application is for cost–effectiveness analyses, which often is a more appropriate procedure to use in evaluating a proposed regulation than is a cost–benefit analysis. A cost–effectiveness analysis will provide the public with information on the incremental cost and benefits of alternative degrees of protection and regulatory severity, thus allowing the choice of that course of action which provides the desired degree of protection at the lowest cost to society. In many cases this will eliminate the need to monetize the various hazards which are being abated, and allow a direct comparison of the desirability of each segment of the rule.

Peer review. An underlying requirement for each of these steps is that the data base be sound, and that the best possible scientific judgment be exercised in its evaluation. It has been recognized by the AIHC and others that it will be necessary

to involve a broad spectrum of scientific expertise in this effort in order to assure that a sound scientific judgment is made. To this end, a proposal has been made by the AIHC for an independent science panel which would, within the context of a national chronic health hazards policy, serve all of the regulatory agencies in the evaluation of the scientific data relating to chronic health hazards (44), and would eliminate the need for policy decisions constraining science, as proposed by the IRLG.

It would be difficult to overemphasize the need for adequate data verification and peer review in all phases of the risk assessment procedure. Beginning with the initial study which first raises the questions of a potential hazard, through to the actual risk estimate calculations, all steps in this process should be conducted with not only opportunity for comment by the public, but also with a deliberate effort to obtain adequate review by acknowledged experts in the relevant fields. The IRLG Task Force not only failed to recognize the importance of peer review in the data evaluation process, but also failed to utilize it in the preparation of their report (45). The greater the uncertainty regarding the facts or the concept involved, the greater is the need for careful scrutiny by qualified persons. It would seem that the concept of an independent science panel for interagency review of the scientific issues is the most effective means of accomplishing this result. It is vital that all steps be based on a sound and current scientific foundation to provide government agencies with a solid basis for deciding what control is necessary to provide adequate and reasonable protection. This will also assist in the separation of the scientific and regulatory functions. When the final decision makers are assured that they have the best scientific data which are available, they will be better equipped to perform the necessary socioeconomic judgment for which they have the responsibility, and can feel assured that their actions are based on a reasonable and sound foundation. The EPA Science Advisory Board Subcommittee on Airborne Carcinogens recognized this need, and urged that the IRLG Document be reviewed by independent scientists (31). This same group disputed its value as a scientific guideline.

Public participation. In addition, the public will have a much better understanding of the degree of protection which it is being given, the costs of that protection, and a clearer concept of the processes by which the decision was reached. A properly informed public is the best protection against potential hazards in the environment, and public participation must be encouraged at all stages of the regulatory process.

Public awareness of and concern for the role of science in cost-benefit analysis has increased tremendously in recent months. Several journals and professional societies dedicated primarily to the subject of risk analysis have been started in the past few months. A recent literature review in *Toxic Substances Journal* (46) contained several hundred articles, most of them published in the last few years. Particularly illustrative of the public interest are the many perceptive responses (47) to a recent article in *Regulation* (48) dealing with the ethical and economic features of cost–benefit analyses, of which risk assessment is a vital part. These correspondents emphasize that society is better served by an informed and considered scientific judgment than by the application of personal value judgments.

It is reasonable to expect that risk assessment can be developed into a much more precise and reliable tool than it now is. One step in that development will be to obtain experience in its use, thus pointing out more clearly the areas where

improvement is needed. Unrealistic expectations should not be raised for this procedure until adequate means have been developed for providing the necessary data base for its application. We must, for example, produce validated experimental data more suitable for use in making quantitative assessments. And, at the same time, more research effort should be put into understanding the mechanisms of carcinogenesis, developing the methods for interspecies comparison and for more effective human epidemiology, and better bioassay protocol design and analysis. These are key areas, and require much more development.

Finally, it will be necessary for the scientific community to accept its responsibility as especially well-informed and capable citizens to participate in the regulatory processes as both critics and contributors. There are many uncertainties which never can be eliminated before a decision must be made to regulate or not, or if so, to what degree. The quantitative risk assessment often is a distillation of many of these uncertainties, but there remains the need to view the whole of the data. Only when the regulator can feel secure in the validity of the data can appropriate risk management decisions be made. It is, therefore, vital that those best able to participate in the evaluation process do so freely and willingly.

SUMMARY

Every regulation is the result of a decision by someone that the results will be worthy of the effort. The need is for a sound process by which such decisions are made. Therefore, it is necessary that we develop a coherent federal policy for the control of chronic health hazards. The current level of public interest and our rapidly developing analytical ability will force many decisions on the regulatory bodies which cannot be made in an effective manner without an adequate framework on which to base those decisions. Thus, a true interagency approach is necessary. This approach must assure the decision makers that the best scientific knowledge has been utilized in developing the data base from which action is taken. All available data must be evaluated carefully for significance. An independent scientific panel appears to be the most effective means of assuring this thorough scrutiny.

The current status of the IRLG draft Report as an informally adopted policy of the regulatory agencies blocks the application of sound science by these agencies in their activities for controlling substances which are potential chronic health hazards. The regulatory policies in this area should be reconsidered carefully, and a necessary step in this reconsideration is a revision of the IRLG draft Report. The AIHC has called for this reconsideration in a letter to the President's Task Force on Regulatory Relief, and has stated its willingness (12) to assist the IRLG in that effort. The process should begin immediately.

ACKNOWLEDGMENTS

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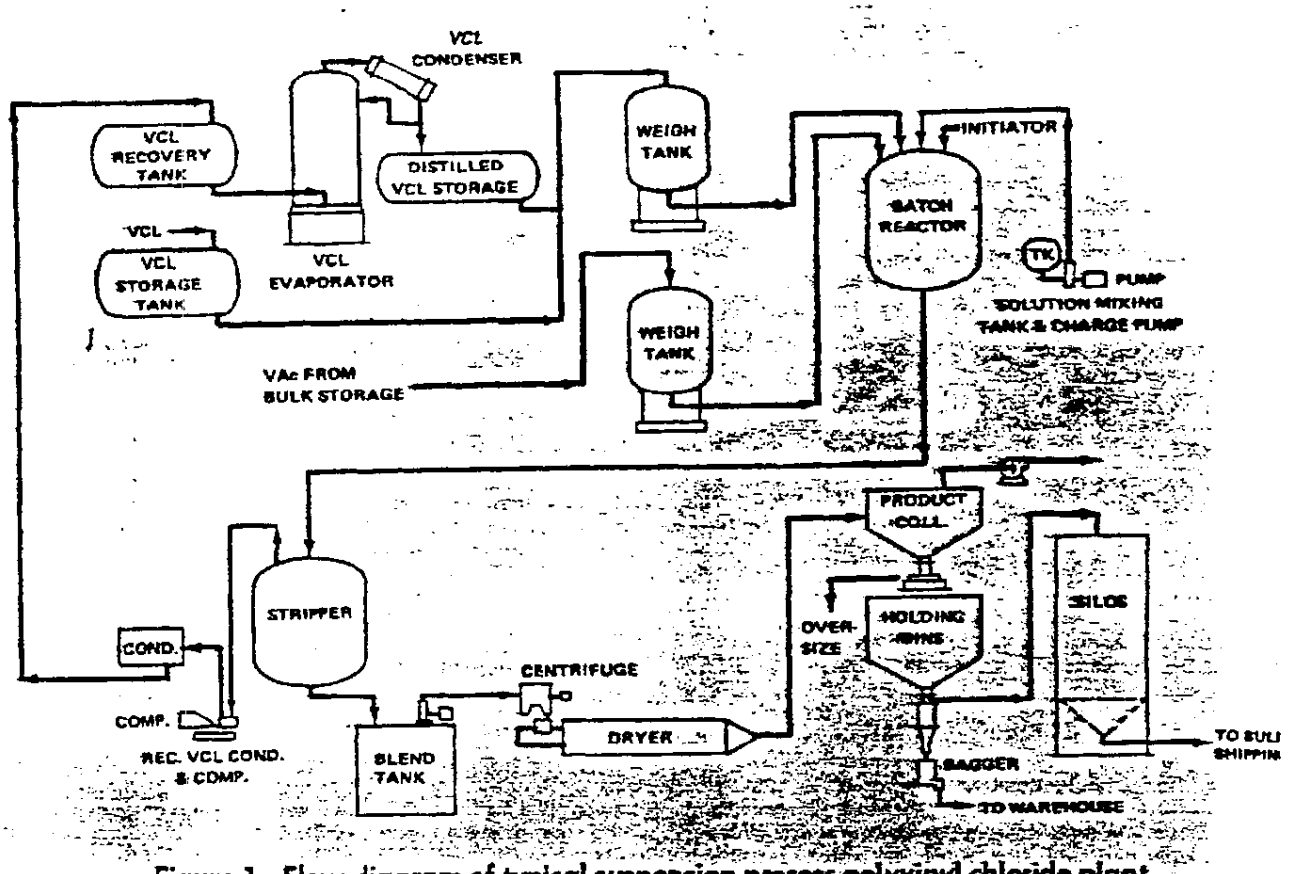

Figure 1. Flow diagram of typical suspension process polyvinyl chloride plant.

EMISSION CONTROL:

Stripping VCM from PVC Resins

Here's a progress report on a stripping technique that can be used in the production of resins by the suspension process.

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Vinyl chloride monomer (VCM) can be stripped from polyvinyl chloride (PVC) resins in aqueous slurries and from dry powder resins. This article reports on the steps that can be used for this purpose in producing resin by the suspension process. Our work is continuing, and many conclusions presented here are preliminary.

A simplified flow diagram for a typical suspension plant is shown in Figure 1. VCM and initiator are dispersed in water by means of agitation and suspending agents, and then polymerized at an appropriate temperature to give the desired resin molecular weight. The reaction cycle is terminated when the rate becomes uneconomical to maintain, or earlier if enhanced porosity is desired. Conversion is normally between 83 and 90%. Most of the unreacted monomer is recovered and recycled to the process, but the last few tenths of a percent historically have been left in the slurry because they are difficult to remove. It is this residual monomer that is

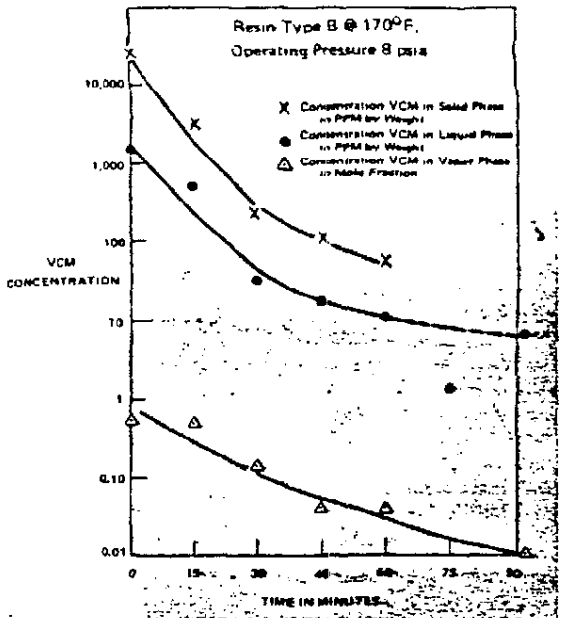

Figure 2. VCM concentration in solid, liquid, and vapor phases as a function of time during plant stripping.

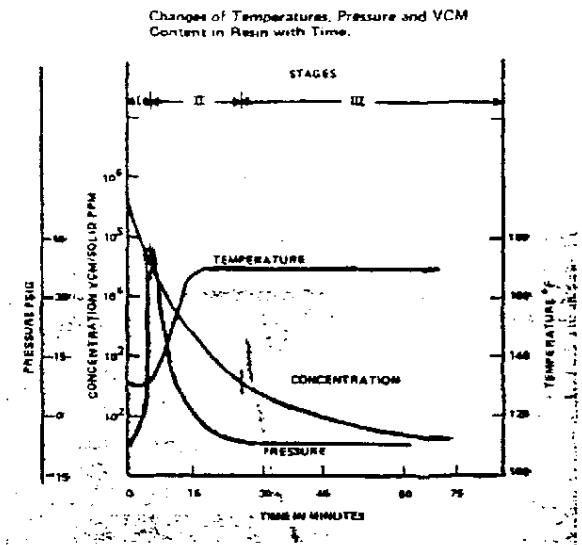

Figure 3. Stages of plant slurry stripping.

now of primary concern.

Monomer is usually recovered by vacuum stripping of the reaction slurry, either in the polymerization reactor or in a special stripping vessel. The monomer so obtained is compressed and condensed for re-use.

After stripping, the polymer slurry is transferred to open equipment, and any remaining free monomer eventually enters the environment. The amount and location of this release depends on the amount of residual monomer, the physical nature of the polymer particles, and processing conditions to which the resin is exposed.

Blends of several batches of polymer are mixed in slurry tanks and pumped to centrifuges for partial dewatering. Drying is done in either cocurrent rotary kiln driers or fluid bed driers. Dried resin is collected and conveyed pneumatically to storage or packaging. Resin may be transferred several times and stored for a few days to a few weeks before it finally reaches the fabricator and is blended with necessary additives and processed into finished goods. During each of these stages there is further loss of monomer, dependent upon time, temperature, partial pressure of monomer over the resin, and properties of resin particles.

Monomer losses during manufacture and stripping

Figure 2 shows a typical curve relating losses of monomer in resins, water, and vapor phases as a function of time during a plant stripping operation. Slurry temperature during this run was 170°F. (77°C.) and pressure was 8 lb./sq.in.abs. The data in Figure 2 were obtained from a plant slurry batch of a Type B resin (described in Table 1) taken to about 85% conversion and transferred to an evacuated stripper. During transfer, the pressure in the stripper rose to about 40 lb./sq.in.gauge in about

Table 1. PVC homopolymer and copolymer resin types used in this study.

Resin	Composition	Description	IPTU* Range	% Accessible Porosity**	Inherent Viscosity dl./gm.
A	PVC	General Purpose Low Porosity	19–21	10–11	0.88–0.92
B	PVC	General Purpose Medium Porosity	26–28	17–18	0.94–0.98
C	PVC	Specialty No Pericellular Membrane High Porosity	30–32	25–26	0.80–0.88
D	Vinyl Acetate Copolymer	—	—	22	0.46–0.50
E-1	Propylene Copolymer	—	16–20	8.5–10	0.70–0.76
E-2	Propylene Copolymer	—	16–20	—	0.57–0.63

*Irreversible plasticizer take up (IPTU) by Method in Carleton and Mischuck. (1)
**By mercury porosimeter according to Chan and Beale. (2)

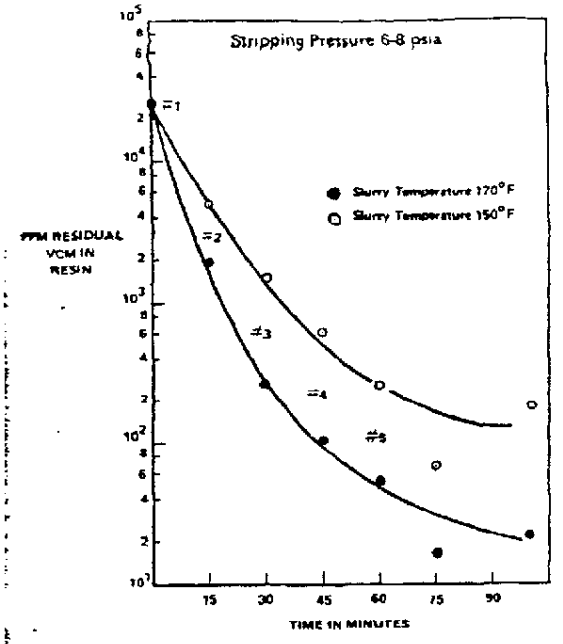

Figure 4. Effect of stripping temperature on VCM loss in Type B resin.

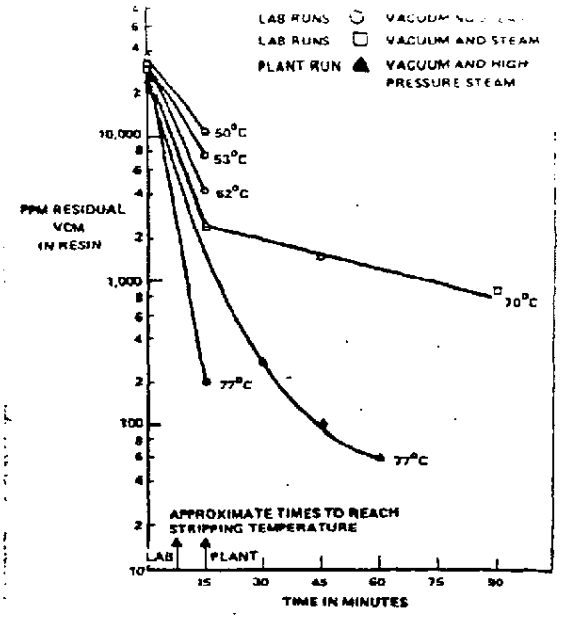

Figure 5. Laboratory vs. plant slurry stripping of Type B resin and temperature effects.

two minutes. With the pump capacity and steam input available, a period of approximately 15 min. was required to reach specified temperature and vacuum. Under these conditions, about 50 parts/million of monomer remains in this medium porosity resin at the end of one hour total resident time in the stripper.

Table 2 lists the processing steps and approximate average losses of VCM at each step. VCM concentrations are relatively high compared with data obtained under improved operating conditions. Our data show that the greatest absolute loss of monomer downstream of the stripper occurs in the blending step. A further 60% loss is also shown in the drying step; with a more porous resin, this can be as high as 80%. Losses at each step vary with conditions. In the example shown, only 5% of the monomer present in resin after stripping remained when tested at the customer's plant.

Three consecutive stages in the stripping process have been defined.

Figure 3 and Table 3 show changes in monomer content, pressure, and temperature that occur in these stages when a batch of slurry is dropped from a reactor into an evacuated stripper.

As noted earlier, there is a very rapid increase in pressure, generally to about 40 lb./sq.in.gauge in the first few minutes, followed by a slower fall to the operating pressure. Operating temperature is reached at about the same time. This is defined as Stage I and generally results in a monomer reduction from approximately 18% in the solid to about 2 to 4% depending upon conditions of the drop. About 80 to 85% of unreacted VCM is removed here. In Stage II residual monomer has dropped to about 500 parts/million. Stage III is where residual monomer is below 500 parts/million and where rates of VCM removal are at their lowest values. Table 3 summarizes approximate monomer losses during the three stripping stages.

Monomer stripping studies covered in this paper gen-

Table 2. Approximate monomer losses after stripping in manufacture of resin Type A.

Process Step	VCM Content End Step, parts/million	Percent Loss in Step
Leaving Stripper	2,000	—
Slurry Blending	800	60
Centrifuging	720	10
Drying	290	60
Storage	215	40
Shipping	105	50

Table 3. Losses of monomer in three stages of stripping of batch from slurry of 10,000 lb. monomer charge.*

	Stages I	II	III
VCM (parts/million) in Resin:			
Initial	180,000	30,000	500
Final	30,000	500	1
Pounds Lost**	1,275	251	4

*Approximate conversion = 85%.

**Approximate weight ratios of monomer in vapor, liquid and solid phases are 1:100:1000 during stripping.

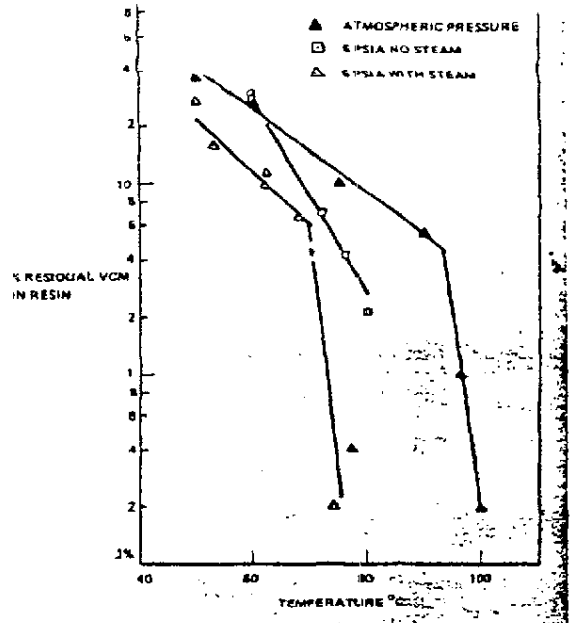

Figure 6. Effects of pressure and steam purge on VCM removal in laboratory stripping of Type B resin (VCM: 45,000 parts/million), stripping time 15 min.

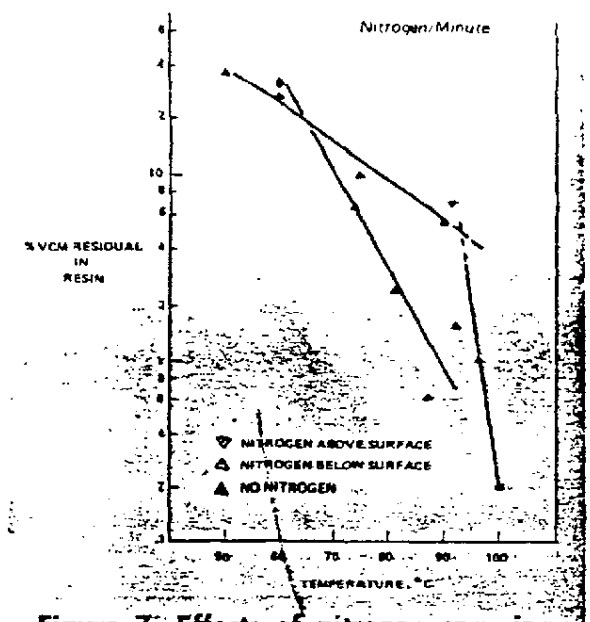

Figure 7. Effects of nitrogen sparging on VCM removal in laboratory, Type B resin (VCM: 45,000 parts/million), stripping time 15 min.

rally begin at Stage II. About 15% of unreacted monomer is removed in this stage.

Within limits of agitation ranges normally available, the degree of agitation did not effect stripping rate. We must assume, therefore, that turnover rates in the slurry are adequate to produce optimum stripping in our plant equipment.

Other factors, however, do have influence on the stripping process. Batches that have been polymerized passed the optimum cut-off point result in lowered resin porosity and slower stripping. In addition, slurry batches which have been cooled in the reactor for scheduling reasons not only require longer time for heating to stripping temperatures, but also appear to give slower stripping rates.

One generalization discussed later is that low molecular-weight resins polymerized at higher temperatures are generally less porous and require longer stripping times than higher molecular-weight resins manufactured with similar recipes at lower temperature.

How the experimental work was carried out

Resins, equipment, and the experimental procedures used in this work are described below.

Resins. Five resin types used in this study, Table 1. Resins A and B are general purpose resins made in recipes which contain a conventional colloid stabilizer. Resin C, produced in laboratory or plant reactors in the absence of the conventional polymeric colloid stabilizer, does not contain a pericellular membrane. Resin C is measurably more porous than A and B, and the primary particle structure can be easily identified using a scanning electron microscope. Other resins listed in Table 1 are copolymer resins containing either vinyl acetate or propylene.

Laboratory studies. Resins A, B, and C, used in the laboratory stripping experiments, were prepared in a 3-1/4 gal. reactor using commercial recipes. Resin slurries after polymerization were cooled, vented, and stored in 1 gal., wide-mouth, glass jars. Aliquot portions were taken at intervals over a period of weeks. No significant losses of monomer occurred in the solid phase during this period.

Table 4. Temperatures of slurry and vapor for resin Type B in plant stripping study.*

Sampling Point*	Time, Min.	High Temperature Run		Low Temperature Run	
		Slurry Temp. °F.	Vapor Temp. °F.	Slurry Temp. °F.	Vapor Temp. °F.
1	0	136	136	132	130
2	15	170	170	152	150
3	30	168	172	151	152
4	45	168	172	150	154
5	60	170	172	150	156

*See Figure 4.

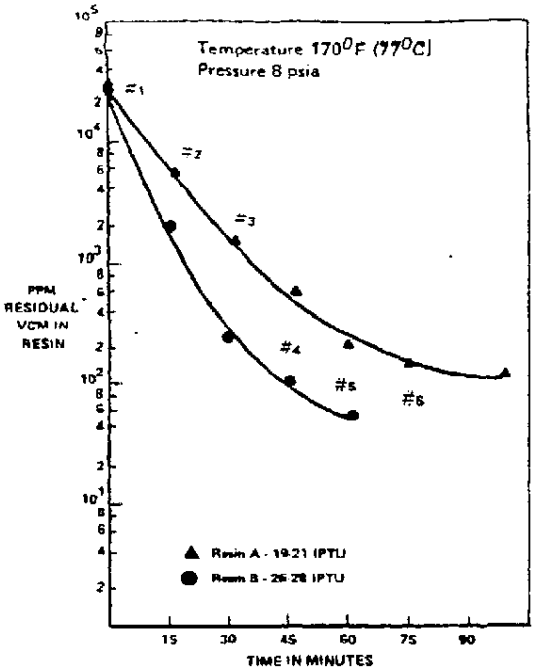

Figure 8. Effect of porosity on VCM removal in plant stripping.

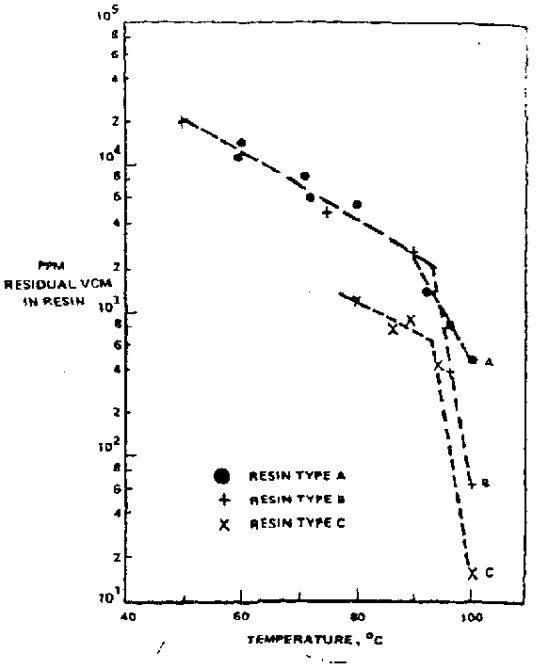

Figure 9. Laboratory stripping of resin Types A, B, and C at atmospheric pressure (VCM: 43,900, 47,000, and 23,400 parts/million, respectively), stripping time 15 min.

Laboratory stripping was conducted in a one-liter, three-necked, glass flask fitted with a Friedrichs condenser. Stirring was supplied by a magnetic stir bar. The slurry mixture from the master batch and added water were mixed, heated rapidly by immersion into a preheated 5 gal. oil bath. The overall water/resin ratio was approximately 2:1. Compressed nitrogen at 5 lb./sq.in. or steam at atmospheric pressure were used in sparging experiments. The water/polymer mixture was sampled before stripping to determine VCM content in resin. At completion of each stripping experiment, a second sample was removed to determine VCM content of resin and in some cases, resin porosity.

Plant studies. A 10,000 gal. stripper, equipped with vacuum and high pressure steam, was used in plant stripping. It was fitted with an agitator just above the steam inlet port near the bottom of the stripper. The procedure for dropping the charge from reactor to stripper was described earlier. Initial samples for analysis at zero time were taken when the pressure rise in the stripper had reached its maximum value before falling.

Analytical samples were removed using a "sampler" of special design located at the bottom of the stripping vessels. This attachment allowed separate collection of slurry and water phases under conditions where no monomer losses occurred.

Analytical procedures. Analysis for VCM in PVC solid was conducted using a solution of the resin in tetrahydrofuran and a gas chromatograph. Impurities in the solvent were removed previously by a passage through a column of basic alumina with or without acitvated carbon. Gas chromatographs were fitted with flame ionization detectors and used nitrogen or helium as carrier gas. Column packing was either Porapak Q or Chromasorb W.

Concentrations of monomer in solid and liquid phases

Table 5. Temperatures of slurry and vapor for resin Types A and B in plant stripping.*

Sampling Point*	Time, Min.	Slurry Temperature, °F.		Vapor Temperature, °F.	
		Resin A	Resin B	Resin A	Resin B
1	0	133	136	136	136
2	15	167	170	170	170
3	30	167	168	172	172
4	45	170	168	174	172
5	60	170	170	175	172
6	75	170	—	175	—
7	100	170	—	175	—

*See Figure 8.

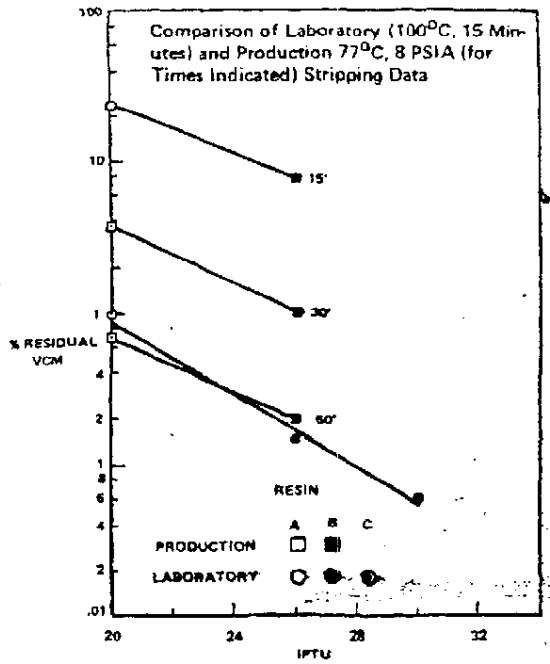

Figure 10. Effect of resin porosity on residual VCM.

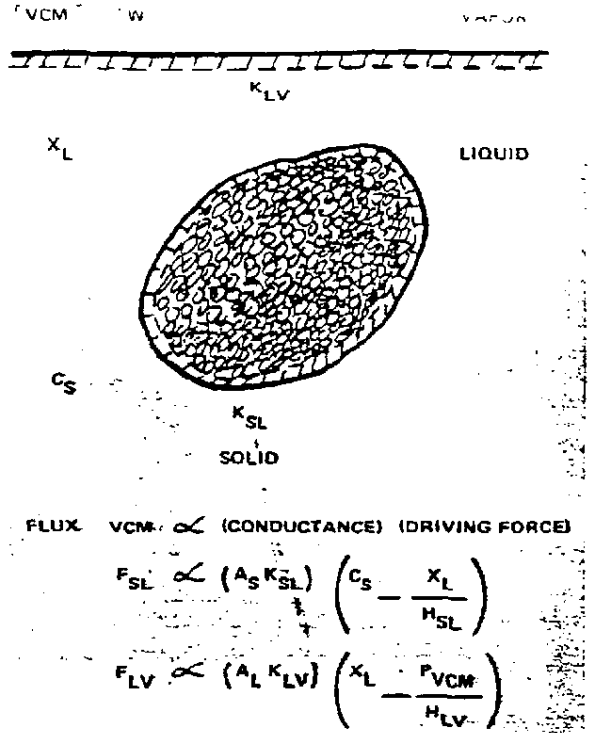

Figure 11. Model for slurry stripping. C_S, X_L, P_{VCM} are concentrations or partial pressure of VCM. K_{LV}, K_{SL} are mass transfer coefficients. H_{LV}, H_{SL} are Henry Law constants. A_S, A_L are areas at S/L and L/V interfaces.

are expressed in parts/million by weight. Concentrations in the gas phase are expressed in mole fraction.

Variables which affect stripping process

The stripping operation is the most effective and safest step for removal of unreacted VCM from PVC resin. The following reports on laboratory and manufacturing plant work designed to establish important process variables and their quantitative effects.

Time, temperature, and pressure. As noted earlier, Figure 2, there is a loss of monomer at a continually decreasing rate with time during a typical plant stripping operating during Stages II and III. Time is an important variable; and under any given set of conditions, the more extended the stripping the lower is the residual monomer in resin and aqueous phases. In the following sections, primary emphasis is given to removal of monomer from the solid resin phase.

Figure 4 is a semi-log plot of residual monomer in a Type B resin as a function of time at two temperatures in a plant stripping study. Slurry and vapor temperatures for the two runs appear in Table 4. From these data, a 20°F. (11°C.) increase in slurry temperature produced an increase in rate of removal in Stage II of approximately two times at the 2,000 to 3,000 parts/million VCM level and an increase of three times at 200 and 300 parts/million in Stage III.

Laboratory scouting experiments were carried out with the medium porosity resin Type B to determine influence of temperature on stripping rate in Stages II and III. The master batch slurry contained about 35,000 parts/million in polymer solids.

Figure 5 is a semi-log plot of data obtained in the temperature range of 50 to 77°C. (122 to 170°F.). In a 15 minute stripping period, an increase of 25°C. (45°F.) decreases residual VCM in the resin by almost two orders of magnitude. Note that at a temperature of approximately 170°F. (77°C.), residual monomer content in this medium was about 200 parts/million after 15 minutes of vacuum stripping.

Temperature has a profound effect on removal of VCM in Stages II and III. For comparison, plant data for a Type B resin are also plotted in Figure 5. At 77°C., rates of VCM removal from the two systems are fairly close,

Table 6. Effect of particle porosity on residual level of VCM in resins stripped in laboratory at 100°C., atmospheric pressure, 15 min.

	A	B	C
Porosity, IPTU*	20	26	30
VCM (parts/million) in Resin			
Initially	43,900	47,000	23,400
After stripping	450	60	15
% Original VCM remaining	1.05	0.13	0.06

*Irreversible plasticizer take-up procedure (7).

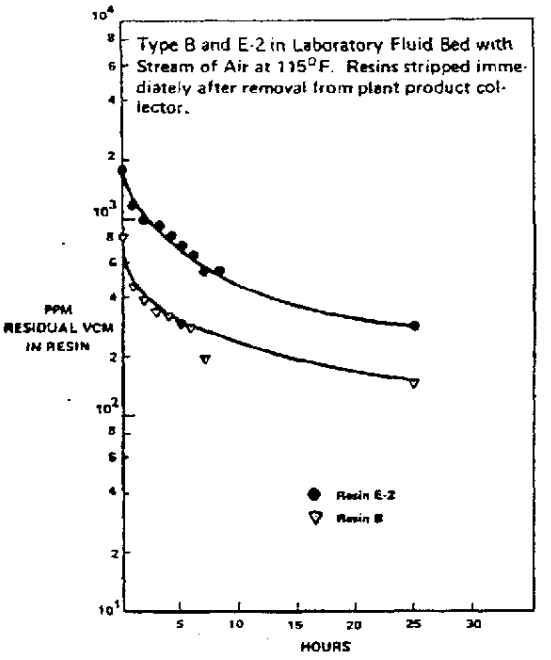

Figure 12. Stripping of VCM from dry PVC resins.

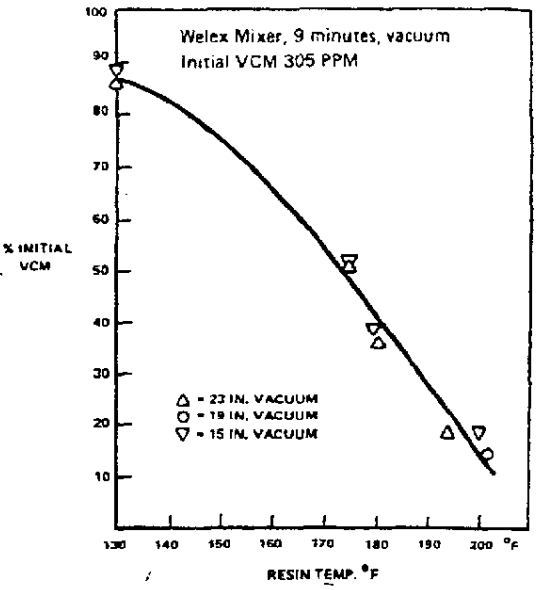

Figure 13. Stripping VCM from solid resin Type E-1 resin (VCM: 305 parts/million).

considering significant differences in procedures, equipment, and times to reach stripping temperature.

Advantages found in use of vacuum and steam

Influences of stripping pressure and steam sparging in laboratory stripping studies are shown in Figure 6. Percentage monomer losses from resin is plotted as a function of temperature at a fixed stripping time of 15 minutes. There is a distinct advantage in using vacuum and a further advantage for vacuum plus steam as opposed to operating at atmospheric pressure.

Remarkable increases in rate of VCM removal are noted at approximately 203°F. (95°C.) under atmospheric stripping conditions and at approximately 158°F. (70°C.) in vacuum stripping with steam. We associate these rate increases with the onset of "pseudo-boiling" or nucleation of a high liquid/vapor interface. The

Table 7. Influence of stripping temperature and pressure on particle porosity in laboratory stripping studies Type B resin.

Resin*	Stripping Conditions, 15 min. Temp. °C.	in. Hg. Vacuum	Resin VCM Content After Stripping	IPTU***
Control	—	—	45,000**	26
a	50	Atm.	18,900	24
b	60	Atm.	14,000	27
c	75	Atm.	4,700	29
d	100	Atm.	40	28
e	53	14	7,400	29
f	62	14	4,100	30
g	68	14	1,000	30
h	77	14	100	31

*Resin in all experiments filtered by suction and dried at 40°C. (104°F.) in a vacuum oven.
**Original VCM content of master batch slurry.
***Irreversible plasticizer take up (1)

nportance of this interface to promote rapid stripping discussed below.

Surface area for evaporation. Type B resin was pped under atmospheric conditions in laboratory ipment using nitrogen sparging to determine influence t a gaseous phase in slurry stripping. Figure 7 shows hat a nitrogen sweep slightly above the surface is without effect. The accelerating effect of nitrogen sparging nto the liquid is temperature-dependent and is greater s stripping temperature is increased. Apparently the iquid-vapor barrier for VCM removal under these laboratory conditions becomes more important as the rate of emoval from the solid phase is accelerated.

Particle structure. Particle micro-structure has an important influence on rate of VCM removal during stripping. Figure 8 is a graphical plot of VCM removal from general purpose non-porous resin A and general purpose medium porosity resin B in plant strippers. Table 5 summarizes slurry and vapor temperature data for these two runs. Data show that the more porous resin B loses monomer at a rate of about 1.5 to 1.8 times faster than resin A at VCM levels between 200 and 2,000 parts/million.

Laboratory studies established influence of resin porosity on stripping rates under atmospheric conditions. Figure 9 and Table 6 summarize results using master batch slurries containing resins Type A, B, and C stripped at temperatures between 60°C. (140°F.) and 100°C. (212°F.) for 15 minutes. We noted an abrupt increase in rate at a temperature close to but measurably below the boiling point of water.

Figure 10 is a plot relating resin porosities of A, B, and C to residual VCM content after 15 min. of stripping at 100°C. For purpose of comparison, data from resins Type A and B plant runs, Figure 8, are plotted also in Figure 10. Response of stripping rate to resin porosity is remarkably similar in these laboratory and plant strippings. An increase of one unit of irreversible plasticizer take up (IPTU) in the range of resin porosity measured, increases stripping rate by about 15% in Stage III.

An unexpected effect on resin porosity was produced by rapid stripping in Stages II and III in laboratory work. Table 7 summarizes stripping conditions and resultant particle porosities as measured by the procedure of Carleton and Mishuck (*1*). Rapid removal of monomer from a PVC slurry containing 4.5% residual VCM in Type B resin markedly increased plasticizer absorption from a value of about 26 to values as high as 31. This phenomenon may be related to the process of producing "blotter" resins where liquid vinyl chloride monomer is removed from resin at low conversion forming a highly porous structure, sometimes referred to as the "popcorn" effect.

Mathematical model found useful

A model for removal of VCM from a PVC particle suspended in an aqueous medium in contact with a vapor phase is shown in Figure 11. From this model, equations relating rates of removal from the three phases as a function of operating variables and polymer properties were developed. The model assumes that there are four barriers for removal of monomer from a suspended particle in an aqueous medium. There are two boundary layers above and below the solid/liquid and liquid/vapor interfaces. Among these, the vapor side boundary layer above the liquid/vapor interface is believed to be of no great importance and for practical purposes can be disregarded.

Calculations using a correlation from Brian, et al. (*3*) show convincingly that the liquid side boundary resistance at the solid/liquid interface is also negligible. This leaves two boundary layers as important: one on the solid side of the solid/liquid interface and one at the liquid side of the liquid/vapor interface.

PVC particles have a micro-porous structure, as discussed in the literature (*1, 4, 5, 6*). Particle diameters in our model relate to primary particles or aggregates of them shown in Figure 11 rather than the diameter of the particle measured by typical screen analysis.

Concentrations of VCM in solid, liquid, and vapor phases are expressed in terms of concentration or VCM partial pressure. Their relationships during a typical stripping operation are shown in Figure 2 for a particular stripping experiment. These are expressed in the model as C_S, X_L, and P_{VCM}, respectively. Mass transfer coefficients of VCM at the barriers for the remaining two important boundary layers are given as K_{SL} and K_{LV}. The model envisions a driving force that is measured as a deviation of VCM concentration from equilibrium in two adjacent phases. It is necessary, therefore, to measure Henry's Law constants for solutions of VCM at equilibrium in the liquid, solid, and vapor phases.

From a consideration of the model, mass balance equations relating rates of losses in solid, liquid, and vapor phases, have been formulated in terms of mass transfer coefficients, pumping capacity, stripper dimensions, the amount of slurry charged, and the vapor pressure of water at the temperature of stripping. We are currently in the process of determining the mass transfer coefficients by a computer assisted curve fitting procedure.

In addition, we are determining Henry's Law constants H_{SL} and H_{LV} at a variety of temperatures. Experimental values obtained for a Stage III slurry at 170°F. (77°C.) are as follows:

For solid/liquid interface:

$$H_{SL} = \frac{X_L}{C_S} \cong 0.08$$

For vapor/liquid interface:

$$H_{LV} = \frac{P_{VCM}}{X_L} = (1.00 \pm 0.05) \times 10^{11} \frac{\text{dyne-cm.}}{\text{g. mole}}$$

$$= 0.024 \pm 0.001 \text{ lb./sq.in./ppm.}$$

This liquid/vapor Henry's Law constant is nearly identical with the value obtained using Berens's VCM water solubility data (*6*) and a vapor pressure of 10,200

Table 8. Influence of temperature in plant drying of Type A Resin.

Inlet Air Temperature, °F.	VCM Residual in Resin: Drier Inlet**	Drier Exit**	% VCM Remaining
280	850	200	24
260	850	350	41
220	1050	500	48

*Rotary drier with capacity of 5,500 lb./hr; residence time 15 min.; air exit temperature approximately 150°F.

**Average of several samples.

mm.Hg. at 76°C.; $H_{LV} = 9.71 \times 10^{10}$ dyne-cm./g. mole. The solid/liquid constant is somewhat lower than the 76°C. value calculated from Beren's liquid vapor and solid/vapor data, using the relation, $H_{SL} = H_{SV}/H_{LV}$; $H_{SL} = 0.10$.

Monomer is stripped from solid resins too

When freshly manufactured PVC resins are "stripped" in a small fluid bed type drier, rates of monomer removal in general resemble rates obtained on monomer slurry stripping. Figure 12 is a plot of residual monomer content obtained with resin Type B and resin Type E-2 as a function of time in fluid bed stripping. Percentage losses from both resins were essentially identical over a 24 hr. period. Under these conditions, approximately 50% of contained residual monomer was removed in 2 to 3 hr. at 115°F.

Very rapid removal of residual monomer from resins is achieved by mixing in an intensive mixer under vacuum at temperatures between 130° and 200°F. (55° and 93°C.). Figure 13 is a plot of residual monomer content of a propylene copolymer resin Type E-1 at various temperatures for 9 minutes in an intensive mixer. At approximately 170°F. (76°C.), 50% of the original monomer content was removed and at 200°F. it was 90%.

Extensive studies in our laboratories, and in others as well, show that in typical compounding operations of this type rapid and nearly complete monomer removal can be achieved at high temperatures with no resin discoloration and no loss of thermal stability.

Influence of drying temperature in a commercial rotary drier in manufacture of Type A resin is summarized in Table 8. As expected, increasing the air inlet temperature in the range of 220 to 280°F. (105° to 138°C.) had a marked effect on the residual monomer content.

Results

Reduction of monomer content in both aqueous and powder stripping work, Figures 2 and 12, show continuing rate losses with time. The curves are similar to those reported by Berens (7) for PVC powders at 90°C. He interpreted reduced monomer losses with time to arise from a lowering of monomer diffusion rates inside particles as monomer content is reduced and in later stages to the presence of glassy particles. Since our glassy particle contents were in the range of 0% to 2%, we do not believe that glassy particles played a dominant role in our work.

We note no discontinuity in Figure 13 for VCM loss in the region of the second order transition temperature of PVC, 160° to 175°F. Hopfenberg and Stannett report a number of examples where no discontinuities in diffusion coefficients were noted in the region of the glass transition temperature for a number of polymers and a number of penetrating gases (8).

Rate controlling processes for VCM in Stages I, II and III of aqueous slurry stripping appear to differ. In Stage I, extremely large amounts of monomer are lost in very short periods of time. It is likely that this process occurs by direct formation of bubbles at the solid/liquid interface which move directly to the slurry liquid/vapor interface. Stage II rates are influenced markedly by temperature, by boiling or nitrogen sparging and by resin porosity.

Present work on our model will establish quantitatively the relative importance of the two important barriers at the solid/liquid and liquid/vapor interfaces. Our work suggests that both are playing a role. It is clear, however, that a boiling or rapid degassing condition in Stage II is necessary to promote optimum rate of VCM removal. We associate increases in monomer removal rates in atmospheric stripping at 90° to 95°C. in Figures 8 and 9 with the start of bubble nucleation. Stage III stripping rates appear to be more dependent upon the solid/liquid interface and on diffusion rates inside resin particles.

The very rapid losses of VCM in Stage I, and rapid increases in rates at about 90°C. in atmospheric stripping, suggests that pseudo-boiling or degassing occurs below the normal boiling point of water. How bubbles form and how they are influenced by primary particle diameter, pore size, and pore distribution remain to be established.

Acknowledgment

We wish to express our appreciation to the many people in the Analytical Dept. of Air Products and Chemicals, Inc., and to many members of the industry who have so generously contributed their knowledge toward the solution of a problem affecting the health and safety of our employees and theirs. It is in this same spirit that we have elected to share our preliminary findings with others in this progress report. We are continuing our work and will report additional findings as they become available.

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