

**The Law and Policy of  
Toxic Substances Control**

**A Case Study of Vinyl Chloride**

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PVC.<sup>546</sup> For now, however, FDA continues to move cautiously. The manufacturers have sued the agency over the acrylonitrile decision,<sup>547</sup> and it may be that FDA intends to await a judicial decision before acting with regard to any other material.<sup>548</sup>

The agency's most serious failure in the regulation of PVC is its unjustifiable delay in decision making. There were indications that VC is carcinogenic as early as 1971. Yet in 1973, when FDA learned that high VC concentrations were leaching from liquor bottles, the agency took no new steps to assess the chemical's toxicity or the amounts leached from other PVC materials. More than two years elapsed between the discovery that VC causes human cancers and FDA's proposed regulations. A proposal probably would not have been made even then without the pressure of the Health Research Group's petition.<sup>549</sup> FDA's interest in regulating PVC at all has itself motivated the manufacturers to reduce the VC residual content of the materials and the levels of VC migration. Interest alone, however, is not action enough to satisfy FDA's duty to ensure the safety of food. The agency has missed at least one self-imposed deadline for completing the proceeding.<sup>550</sup> Meanwhile, all PVC food-contact materials—even ones with detectable migration—remain in unrestricted use.

*E. The Aerosol Bans—The Food, Drug, and Cosmetic Act, The Federal Environmental Pesticide Control Act, and the Federal Hazardous Substances Act*

*1. The Key Issues in the Regulation of Aerosols*

Two areas where regulatory jurisdiction is especially fragmented are the regulation of VC-propelled aerosols and the regulation of the chemical's transportation. Preceding sections have shown that agencies find the problems of decision making under uncertainty and balancing health and economic interests quite difficult. The next two sections show the complicating effect that jurisdictional fragmentation can have on the decision making process.

Fragmented jurisdiction has two particularly deleterious features. First, it creates opportunities for one agency facing a difficult problem or contro-

546. See text accompanying notes 538-539 *supra*.

547. *Monsanto Corp. v. Kennedy*, No. 77-2023 (D.C. Cir., filed Nov. 17, 1977). Challenges also have been filed by other companies and by the Society of the Plastics Industries; the cases are likely to be consolidated.

548. This is the opinion of the General Counsel for the Society of the Plastics Industries. Personal communication with Jerome Heckman, General Counsel, The Society of the Plastics Industries, Dec. 19, 1977. In fact, FDA has not yet extended the acrylonitrile decision even to the chemical's uses in food-contact materials other than bottles. *FDA Acrylonitrile Decision*, *supra* note 484, at 45,841. FDA's position is correct, even though it has fairly drastic results. The agency should not be reluctant to apply the rule to other materials.

549. Personal communication with Stuart Pape, Associate Counsel, Food and Drug Administration, Dec. 29, 1976.

550. See note 537 *supra*.

versial issue to argue that another agency should handle it, or simply to delay action with the hope that another agency will step forward. Second, the statutes may differ from one another—even if only marginally—on such issues as burdens of proof, the amount of evidence of harm needed to support regulation, and whether economic factors may be considered.

Hence, outcomes may differ depending upon which statute is applied. Differences among the statutes create an incentive for industries, consumer and environmental groups, and the agencies themselves to struggle over which statute and agency should regulate a substance. The importance of these two features—the tendency of agencies to avoid difficult or controversial regulatory issues and the possibility of reaching different results under different statutes—is magnified where problems of uncertainty and balancing are great, because the parties have greater reason to believe that the minor differences among the statutes will yield different regulatory results. Conversely, in decisions where these problems are relatively minimal, jurisdictional fragmentation also is less important.

Prior to 1973, VC was widely used as a propellant in a broad range of aerosol products, including cosmetics, drugs, and pesticides. Because of increases in the price of VC, sometime in late 1973 or early 1974 all of the manufacturers of aerosol products stopped using the chemical as a propellant.<sup>551</sup> Nevertheless, when the human cancer hazard was identified in January 1974, there were still at least three and a half million cans containing VC in the possession of manufacturers, distributors, and consumers.<sup>552</sup> All three of the agencies with jurisdiction over these cans—FDA, EPA, and

551. The exact date on which manufacturers stopped using VC as an aerosol propellant is uncertain. Probably they did not all stop at the same time. At one point FDA noted that some manufacturers had stopped using the chemical before 1973. FDA, *Vinyl Chloride as an Ingredient of Drug and Cosmetic Aerosol Products*, Notice of Proposed Rule Making, 39 Fed. Reg. 14,215, 14,216 (1974) (hereinafter cited as *FDA Proposed VC Aerosol Ban*). CPSC stated that the use of VC had ended in early 1974. CPSC, *Self-Pressurized Household Substances Containing Vinyl Chloride*, Notice of Environmental Assessment and Reconsideration, 40 Fed. Reg. 11,170, 41,171 (1975) (hereinafter cited as *CPSC VC Environmental Assessment*). All indications are that the use of VC was ended for financial reasons. Personal communication with Judy Pitcher, Acting Director, Division of Special Economic Studies, CPSC, Jan. 30, 1978. There is no evidence that any company's cessation of VC use before the Goodrich disclosure in January 1974 was motivated by insider's information about the cancer hazard.

552. This estimate is probably on the low side. CPSC estimated that there were about 3.3 million cans containing VC on the market that were subject to its jurisdiction. *CPSC Environmental Assessment*, *supra* note 551, at 41,171. Most uses of VC as a propellant apparently were under CPSC's control. Personal communication with Judy Pitcher, *supra* note 551. FDA noted that the 1973 production of hair sprays containing VC by just two companies was more than 1.6 million units. *FDA Proposed VC Aerosol Ban*, *supra* note 551, at 14,215. According to EPA figures there were at least 19,000 pesticide aerosol cans containing VC on the market. EPA, *Vinyl Chloride, Emergency Suspension Order Concerning Registrations for Certain Products and Intent to Cancel Registrations*, 39 Fed. Reg. 14,753 (1974) (hereinafter cited as *EPA VC Aerosol Suspension*). Thus, it is likely that the number of cans on the market in early 1974 exceeded 3.5 million cans. The difficulty of establishing the exact number illustrates the problems of information gathering that result from jurisdictional fragmentation.

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the Consumer Product Safety Commission (CPSC)—acted quickly in response to the VC aerosol hazard. In the first nine months of 1974, even before OSHA completed its promulgation of the workplace standard, the three agencies banned the future use of VC as a propellant and ordered or requested manufacturers to recall stocks currently on the market.<sup>553</sup>

Since the manufacturers had already stopped using the substance in aerosols, the recall orders and requests were the only disputed aspect of the regulations. Manufacturers sought judicial review only of the CPSC regulations, which were the only ones with a mandatory recall. In 1977, after a long delay, the Ninth Circuit Court of Appeals vacated these regulations on procedural grounds.<sup>554</sup> In March 1978, CPSC repromulgated the prospective portion of the ban, dropping the now largely moot attempt to obtain the recall of existing stocks.<sup>555</sup>

The major reason for the prompt regulatory action by these agencies was the fact that regulating aerosols presented the agencies with no serious balancing issue. The discussion below examines the actions of these three agencies more closely; its major purpose, however, is to expose the differences among the applicable statutes and to demonstrate the potential for jurisdictional conflict in regulating a substance that requires more difficult choices to be made.<sup>556</sup>

## 2. The Statutes Governing Aerosol Products

The following discussion presents the relevant portions of the statutes under which the three agencies addressed VC aerosols. There are substantial differences among the statutes in terms of burdens of proof and criteria for determining if a substance may remain in use. Even though the agencies' decisions were more or less a foregone conclusion in this relatively easy case, these statutory differences would likely become important in a more difficult case.

553. FDA, *Vinyl Chloride as an Ingredient of Drug and Cosmetic Aerosol Products*, 39 Fed. Reg. 30,810 (1974) [hereinafter cited as *FDA VC Aerosol Ban*]; EPA *VC Aerosol Suspension*, supra note 552; CPSC, *Self-Pressurized Household Substances Containing Vinyl Chloride Monomer, Classification as Banned Hazardous Substance*, 39 Fed. Reg. 30,112 (1974) [hereinafter cited as *CPSC VC Aerosol Ban*].

554. *Pactra Indus., Inc. v. CPSC*, 555 F.2d 677 (9th Cir. 1977). The court held that CPSC had improperly denied the aerosol manufacturers a hearing where they could dispute the need for recalling the products on the market. *Id.* at 684 (construing the hearing provisions of FDCA § 701(e), 21 U.S.C. § 371(e) (1970), made applicable to CPSC's actions under the Federal Hazardous Substances Act, § 3(a)(2), 15 U.S.C. § 1261(a)(2) (1970)). The case is discussed further in notes 580, 605 *infra*.

555. CPSC, *Self-Pressurized Household Substances Containing Vinyl Chloride Monomer, Classification as Banned Hazardous Substance*, 43 Fed. Reg. 12,308 (1978) [hereinafter cited as *CPSC Reinstatement of VC Aerosol Ban*].

556. For example, the next section of the Article considers the regulation of VC in transportation, where the problems of fragmentation are more evident.

Although a lay person probably would consider VC aerosol products to be one undifferentiated group, regulatory authority over the products was divided three ways along complex lines. FDA had jurisdiction over VC-propelled "drugs" under the 1962 New Drug Amendments to FDCA<sup>557</sup> and over "cosmetics" under provisions of FDCA dating from 1938.<sup>558</sup> EPA was responsible for VC-propelled "pesticides" under the 1972 Federal Environmental Pesticide Control Act (FEPCA).<sup>559</sup> The remainder of VC-propelled products suitable for consumer use were "household substances" subject to CPSC regulation under the 1966 amendments to the Federal Hazardous Substances Act (FHSA).<sup>560</sup> Whether a substance is a drug, a cosmetic, a pesticide, or a household product is not always clear.<sup>561</sup>

Generally speaking, controls on drugs and pesticides are more stringent than those on cosmetics or household products. For the former pair, the burden is on the proponent of use to show that a substance is safe, rather than on the agency to show that it is unsafe. Under the New Drug Amendments, the proponent must show that a new drug, including its components, is "safe" and effective for its intended use before FDA may permit it to

557. A drug is defined as any article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." FDCA § 201(g)(1)(B), 21 U.S.C. § 321(g)(1)(B) (1970). Each component of such articles is considered a drug. *Id.* § 201(g)(1)(D).

558. Cosmetics are defined as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance," and their components. *Id.* § 201(i), 21 U.S.C. § 321(i) (1970).

559. Pub. L. No. 92-516, 86 Stat. 983, 7 U.S.C. §§ 136-136y (Supp. V 1973), amending the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 135-135k (1970). FEPCA defines a pesticide as:

(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant.

FEPCA § 2(u), 7 U.S.C. § 136(u) (Supp. V 1973). A mixture of substances includes both active and so-called "inert" ingredients, such as propellants. *Id.* § 2(a), (m).

For a general description of the statute, its basic principles, and the legislative history, see Comment, *The Federal Environmental Pesticide Control Amendments of 1972: A Compromise Approach*, 3 *Ecology* L. Q. 277 (1973) [hereinafter cited as *FEPCA: A Compromise Approach*].

560. Pub. L. No. 89-756, § 3(a), 80 Stat. 1303 (1966), adding 15 U.S.C. § 1261(q) (1970). FHSA applies to hazardous substances found or used in households. 15 U.S.C. § 1261(p), (q)(1) (1970). Hazardous substances are defined in pertinent part as:

Any substance or mixture of substances which is (i) toxic . . . if such substance's [a/c] or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or foreseeable handling or use

*Id.* § 1261(f)(1)(A) (1970). Pesticides subject to FEPCA and foods, drugs, and cosmetics subject to FDCA are now excluded from this definition. *Id.* § 1261(f)(2) (Supp. V 1973). A toxic substance is defined as having "the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." *Id.* § 1261(g) (1970).

The administration of FHSA was transferred in 1972 from FDA to CPSC by the Consumer Product Safety Act. *Id.* § 2079(a) (Supp. V 1973).

561. See text accompanying note 608 *infra*.

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enter commerce.<sup>562</sup> When doubts arise as to the safety or effectiveness of a drug already in use, the proponent of continued use must refute these doubts or approval for use must be withdrawn.<sup>563</sup> To register a pesticide under FEPCA, i.e., to obtain a permit for its use, the proponent must show that the product and its components are effective for their intended use and that under customary use they will not cause "unreasonable adverse effects on the environment."<sup>564</sup> As with drugs, when evidence arises that a registered pesticide is causing unreasonable adverse effects, the proponent of continued use must refute the evidence.<sup>565</sup> If the proponent fails, EPA must cancel the product's registration.<sup>566</sup>

For both drugs and pesticides, the agencies can suspend a substance's approval or registration—i.e., order an immediate halt to its use after opportunity for a very limited and brief hearing—if the substance presents an imminent hazard of harm.<sup>567</sup> In addition, EPA may order an emergency suspension of a pesticide, effective without any prior hearing, when the harm is so imminent that the time required for the hearing would allow the harm to occur.<sup>568</sup>

562. FDCA § 503(d), 21 U.S.C. § 355(d) (1970).

563. *Id.* § 503(e), 21 U.S.C. § 355(e) (1970). If a drug was generally recognized as safe and effective by qualified experts in 1962, it was grandfathered past the requirement applicable to new drugs that the applicant show safety and effectiveness. *Id.* § 201(p)(1), 21 U.S.C. § 321(p)(1) (1970). These, however, become subject to regulation as new drugs whenever new information contradicts their general recognition as safe or effective. This was the case with VC-propelled drugs.

564. FEPCA § 3(c)(5)(C)-(D), 7 U.S.C. § 136a(c)(5)(C)-(D) (Supp. V 1973). "Unreasonable adverse effects on the environment" is defined as

any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.

*Id.* § 2(bb), 7 U.S.C. § 136(bb) (Supp. V 1973). EPA may classify a pesticide (i.e., restrict its uses) as necessary to prevent unreasonable adverse effects. *Id.* § 3(d)(1)(B), 7 U.S.C. § 136a(d)(1)(B) (Supp. V 1973).

565. *Id.* § 3(b), (d), 7 U.S.C. § 136a(b),(d) (Supp. V 1973).

566. *Id.*

567. FDCA § 503(e), 21 U.S.C. § 355(e) (1970); FEPCA § 6(c)(1), (d), 7 U.S.C. § 136d(c)(1), (d) (Supp. V 1973). FDCA does not define the circumstances that create an imminent hazard. Under FEPCA, an imminent hazard

exists when the continued use of a pesticide during the time required for cancellation proceeding [sic] would be likely to result in unreasonable adverse effects on the environment . . . .

*Id.* § 2(f), 7 U.S.C. § 136(f) (Supp. V 1973).

Some cancellation proceedings may last as long as two years, and the suspension decision is to take account of the likely length of cancellation proceedings. Therefore, as the length of those proceedings increases, more harms meet the definition of imminence, and it becomes more likely that suspension should be ordered. See *Environmental Defense Fund v. EPA*, 465 F.2d 528, 340, 4 ERC 1523, 1531 (D.C. Cir. 1972); *Environmental Defense Fund v. EPA*, 510 F.2d 1292, 1300, 7 ERC 1689, 1692-93 (D.C. Cir. 1975). See generally Spector, *Regulation of Pesticides by the Environmental Protection Agency*, 5 *Ecology* L.Q. 233 (1975).

568. See note 567 *supra*. Under FEPCA, EPA may also make regulations for the safe disposal of pesticides whose registrations have been cancelled. FEPCA § 19, 7 U.S.C. § 136g (Supp. V 1973). In 1974, under the 1970 Solid Waste Management Act, Pub. L. No. 91-512, §

In all of these determinations, with the exception of emergencies noted above, proponents of the use of drugs and pesticides have the right to adjudicatory hearings.<sup>569</sup> In fact, the drug and pesticide laws provide for the most formal, trial-type proceedings of all the toxic substances control statutes.<sup>570</sup> Both EPA and FDA must support their determinations concerning approvals and registrations with substantial evidence in the record.<sup>571</sup>

Both agencies may seize products from the market if they lack or have lost the required approval or registration.<sup>572</sup> Neither agency, however, has the authority to order manufacturers to recall supplies of such products from distributors and consumers, potentially a more powerful remedy than bringing many separate seizure actions. However, both agencies may request that the manufacturers recall the products voluntarily, holding in reserve the threat of seizure actions. Manufacturers generally attempt to avoid seizure actions because they often result in widespread unfavorable publicity.

Controls on cosmetics and household products are not so stringent. For these products, the agencies have the burden of showing that a substance is unsafe. A cosmetic is "adulterated" under FDCA if it contains a "poisonous or deleterious substance which may render it injurious to users" when used according to labeled instructions or as is customary.<sup>573</sup> To control a dangerous cosmetic FDA must sue the manufacturer or distributor in federal district court, seeking a finding that the product is adulterated and an injunction against its sale.<sup>574</sup> The agency may also seize products that

104, 84 Stat. 1227 (1970), EPA could issue non-enforceable guidelines for the disposal of any hazardous waste. The 1970 Act was superseded by the 1976 Resource Conservation and Recovery Act, 42 U.S.C.A. §§ 6901-6931 (West Supp. 1978), under which the agency may set binding rules for the disposal of such substances. RCRA is discussed in text accompanying notes 722-731 *infra*.

569. FDCA § 503(d)-(e), 21 U.S.C. § 355(d)-(e) (1970); FEPCA § 6(d), 7 U.S.C. § 136(d) (Supp. V 1973).

570. With respect to FEPCA, Congress is now considering an amendment that would reduce the administrative burden of conducting adjudications for each pesticide registration. Under this amendment, the major focus of EPA's regulation would be on the ingredients, or groups of ingredients common to numerous individually registered products, rather than on the products themselves. EPA would set generic standards for these ingredients through rulemaking proceedings, evaluating whether they can be used without "unreasonable adverse effects on the environment." The agency then would apply the relevant generic standards to individually registered products in adjudications. But since the major issues concerning the acceptability of the central ingredients already would have been resolved, the adjudication could be a short, perhaps summary, proceeding. See S. 1698, 95th Cong., 1st Sess. § 3 (1977); H.R. 8681, 95th Cong., 1st Sess. § 4 (1977). For discussion of these amendments, see Schutberg, *The Proposed PIFRA Amendments of 1977: Untangling the Knot of Pesticide Registration*, 2 *HARV. ENV'T L. REV.* -- (1978) (in press).

571. FDCA § 503(f), 21 U.S.C. § 355(f) (1970); FEPCA § 14(b), 7 U.S.C. § 136a(b) (Supp. V 1973).

572. FDCA § 304, 21 U.S.C. § 334 (1970); FEPCA § 13, 7 U.S.C. § 136k (Supp. V 1973).

573. FDCA § 601(a), 21 U.S.C. § 361(a) (1970).

574. FDCA §§ 301-302, 21 U.S.C. §§ 331-332 (1970). For further discussion, see note 971 *infra*.

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probably will be found to be adulterated.<sup>575</sup> While to support an action regarding drugs the agency needs only substantial evidence, FDA must prove its case against a cosmetic by a preponderance of evidence, the normal standard in civil actions. The difficulty of carrying this burden, however, is mitigated by the fact that FDA need show only that the substance "may" be injurious.<sup>576</sup> In practice, FDA can approximate the effect of a banning rule for cosmetics by publishing a notice of products it intends to seize and complain against, giving the grounds on which the agency believes the action would be upheld.<sup>577</sup>

For hazardous household products, the primary purpose of FHSA is to reduce dangers by requiring cautionary labeling and protective packaging.<sup>578</sup> CPSC may ban a substance when the agency finds that labeling and packaging requirements would not provide sufficient protection and that "the objective of the protection of the public health can be adequately served" only by a ban.<sup>579</sup> A person affected by such a rule has the opportunity for a hearing.<sup>580</sup> Rules made under FHSA, unlike the drug and pesticide rules, must be made on "a fair evaluation" of the evidence in the record of these proceedings.<sup>581</sup>

CPSC's powers to remove a dangerous household product from the distribution network are broader than FDA's or EPA's. Like the other agencies, CPSC may seize products in commerce.<sup>582</sup> In addition, the agency

575. FDCA § 304, 21 U.S.C. § 334 (1970). See *Ewing v. Myrtinger & Casselberry, Inc.*, 339 U.S. 594 (1950) (upholding pre-suit seizure when probable cause exists that the substances are adulterated).

576. FDCA § 601(a), 21 U.S.C. § 361(a) (1970).

577. This is how FDA proceeded against VC-propelled cosmetics. It promulgated 21 C.F.R. § 700.14 (1977), which essentially is a statement of position on the agency's readiness to sue to remove any such products from the market. See *FDA VC Aerosol Ban*, *supra* note 553, at 30,830.

578. FHSA §§ 2(p), 3(b), 15 U.S.C. §§ 1261(p), 1262(b) (1970).

579. *Id.* § 2(a)(1), 15 U.S.C. § 1261(a)(1) (1970).

580. *Id.* § 3(a)(2), 15 U.S.C. § 1262(a)(2) (1970), requires that rules declaring a substance to be banned must be set according to the procedures of FDCA § 701(c), 21 U.S.C. § 371(c) (1970). Section 701(e)(1) calls for issuance of a proposal, a period for written or oral comments, and then promulgation of a rule. Section 701(e)(2) permits one adversely affected by such a rule to file objections to the rule and request a public hearing up to 30 days after the promulgation date. Such a filing stays the rule until CPSC holds the hearing and responds to the objections. The provision for a hearing after the promulgation date, rather than within the comment period, is unusual. CPSC's refusal to grant such a hearing was the Ninth Circuit's ground for vacating the agency's VC regulations. *Patra Indus., Inc. v. CPSC*, 555 F.2d 677 (9th Cir. 1977), discussed further in note 603 *infra* and accompanying text.

581. FHSA directs CPSC to follow the provisions of FDCA § 701(e) except with regard to the standard of proof that CPSC and a reviewing court must use. In this regard FHSA instructs the agency to apply the "fair evaluation" standard of FDCA § 409(f)(2), (g)(3), 21 U.S.C. § 348(f)(2), (g)(3) (1970). FHSA § 3(a)(2), 15 U.S.C. § 1262(a)(2) (1970). The "fair evaluation" standard, which has never been explicated by a court, is discussed in note 490, *supra*, and in text accompanying notes 975-985 *infra*.

582. FHSA § 6, 15 U.S.C. § 1265 (1970).

may order manufacturers to recall and repurchase banned substances from distributors and consumers.<sup>583</sup>

The statutes applicable to aerosols take different positions on whether the harmfulness of a substance must be balanced against its utility. FEPCA's requirement that adverse effects be "unreasonable" explicitly requires EPA to balance a pesticide's health and environmental effects against its agricultural and economic benefits.<sup>584</sup> FHSA's standard that a ban be the only means of "adequately" protecting public health requires that CPSC seek less burdensome means of controlling a hazard. It is possible that the term also implies an obligation to balance health costs and economic benefits.<sup>585</sup> In contrast, FDCA's controls over drugs and cosmetics are modified by no adjective or adverb that requires FDA to undertake such balancing; nothing but health considerations are to enter into its decisions.<sup>586</sup>

### 3. Agency Actions Against VC as an Aerosol Propellant

In February 1974, within a month of the discovery of VC's human carcinogenicity, the Health Research Group petitioned the three agencies to ban the use of the chemical as a propellant and to recall the products then on the market.<sup>587</sup> FDA commenced action first. The agency proposed a ban on drug and cosmetic uses in April, citing generally the evidence at that time of cancer in humans and animals.<sup>588</sup> FDA noted that peak exposures from aerosols could exceed routine occupational exposures. The agency did not cite any precise figures on VC's toxicity, nor did it consider benefits or substitutes. FDA announced that it had asked drug and cosmetic manufac-

583. *Id.* § 15, 15 U.S.C. § 1274 (1970).

584. See generally *Spector*, *supra* note 567, at 235-36.

585. In its VC proceedings, CPSC put forward a somewhat equivocal statement of its views on this question:

Although the Commission is not required by the Federal Hazardous Substances Act to consider the economic consequences of its actions, as a matter of policy the Commission has weighed economic factors in deciding upon courses of action.

CPSC, *Self-Pressurized Household Substances Containing Vinyl Chloride Monomer, Ruling on Objection*, 39 Fed. Reg. 36,576, 36,577 (1974) (hereinafter cited as *CPSC Ruling on Objection to VC Recall*).

586. The bare term "safe" in FDCA § 505(e), 21 U.S.C. § 355(e) (1970), might be interpreted to mean that a new drug must be absolutely safe. However, the statute is generally taken to allow FDA to weigh risks of a drug's side-effects against the health benefits that it offers. See generally *Merrill, Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 9-12 (1973). Thus, to postulate the extreme case, drugs are permitted for the treatment of otherwise terminally ill patients if they promise a chance of cure or mitigation, even if they also carry a risk of highly dangerous side-effects. This balancing, however, does not extend to any economic benefits the drug may have, which may not be balanced against side-effects. *Id.*

587. The Health Research Group's Petition to CPSC is printed as an appendix to CPSC's proposal. CPSC, *Self-Pressurized Household Substances Containing Vinyl Chloride, Proposed Classification as a Banned Hazardous Substance*, 39 Fed. Reg. 18,115, 18,116-17 (1974) (hereinafter cited as *CPSC Proposed VC Aerosol Ban*). Health Research Group filed substantially identical petitions with FDA and EPA the same day. Health Research Group, Public Citizen's Health Research Group Asks for Ban on Vinyl Chloride as a Propellant in Aerosols (Feb. 21, 1974) (press release).

588. *FDA Proposed VC Aerosol Ban*, *supra* note 551, at 14,215-16.

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urers to recall voluntarily the products remaining on the market and that several already had done so.<sup>589</sup> The agency proposed two regulations, one removing the drugs' certification of safety, and the other deeming the cosmetics adulterated.<sup>590</sup> Apparently not persuaded that the situation presented an imminent hazard, FDA did not immediately suspend the drugs' certification.<sup>591</sup> The rules were promulgated in August.<sup>592</sup>

EPA acted next and was the first agency to take final action. Several days after FDA's proposal, apparently differing with that agency on the imminence of the hazard, EPA issued an emergency suspension of VC-propelled pesticides.<sup>593</sup> EPA requested the manufacturers to recall existing stocks.<sup>594</sup> To support the emergency suspension EPA cited the fact that at least 14 workers already had died of liver angiosarcoma, and that VC had been shown to cause cancer in animals at levels as low as 50 ppm. The agency termed this evidence "strongly suggestive" of causation. EPA had recently completed tests showing that aerosol users might be exposed to short-term concentrations of up to 400 ppm. The agency concluded that although the health implications of short-term exposures were uncertain, the only "prudent" step was to assume that any exposure to VC increased one's cancer risk.<sup>595</sup> Regarding the economic consequences of its action, EPA noted that there were few economic benefits associated with the use of VC as a propellant, that substitute propellants were readily available, and that no pesticide product would be made unavailable by the ban.<sup>596</sup>

In May, CPSC proposed an order to ban VC-propelled aerosols and to require their repurchase.<sup>597</sup> The agency cited the evidence upon which FDA and EPA had relied. Applying the analysis required under FHSA, CPSC concluded that lesser measures such as a warning label would not provide sufficient protection, particularly since no new VC-propelled products were

589. *Id.*

590. *Id.* At the same time FDA also called for information on VC levels in food, drugs, and cosmetics packaged in PVC, and on the risks therefrom. See note 607 *infra*.

591. Neither the proposal nor the statement accompanying the promulgation, *FDA VC Aerosol Ban*, *supra* note 533, shows that FDA ever formally considered using its suspension powers.

592. *Id.*

593. *EPA VC Aerosol Suspension*, *supra* note 552, at 14,753.

594. *Id.*

595. *Id.* at 14,753-54.

596. *Id.* at 14,754. EPA gave notice of its intent to cancel these registrations unless a hearing were requested, or unless the manufacturers amended their registrations to demonstrate that VC was no longer used. *Id.* No one requested a hearing, and the registrations that were not properly amended were formally cancelled in January, 1975. EPA, *Vinyl Chloride, Pesticide Products Containing Vinyl Chloride*, 40 Fed. Reg. 3,494 (1975).

Although under FEPCA the agency had the authority to promulgate binding regulations for the disposal of recalled aerosols, EPA confined itself to preparing non-binding guidelines in early 1975 for safely incinerating or burying them. EPA, *Vinyl Chloride, Recommended Procedures for Disposal of Aerosol Cans*, 41 Fed. Reg. 23,226 (1976). See note 568 *supra*.

597. *CPSC Proposed VC Aerosol Ban*, *supra* note 587.

being made and the hazard came from those already on the market. The agency concluded that a ban and repurchase was required in order to protect consumers' health adequately.<sup>598</sup>

The CPSC proposal appears to have been the only one to raise significant objections from manufacturers. During the comment period, some manufacturers objected that the health risks were too small to justify imposing on manufacturers the expense of recalling existing products.<sup>599</sup> In August, CPSC rejected this contention and promulgated the rule, scheduled to become effective in October.<sup>600</sup> To controvert the manufacturers' objections the agency relied on the evidence of harm cited in the proposal, on reports of additional liver angiosarcoma cases in the interval since the proposal, and on the manufacturers' failure to suggest a safe level of exposure. CPSC concluded that the risks were sufficiently large and immediate to justify the expense of the recall.<sup>601</sup> The manufacturers then requested a hearing on the evidence.<sup>602</sup> In October, CPSC rejected the request, concluding that the manufacturers had not raised any "factual information which the Commission believes would lead to a conclusion contrary to that reached by it."<sup>603</sup> The agency stated that the manufacturers' disagreement with the agency as to the measures that the facts justified under FHSA was a legal and policy matter not capable of resolution in an evidentiary hearing.<sup>604</sup> The Ninth Circuit held that, on the contrary, a hearing was statutorily mandated, and vacated CPSC's regulations in the spring of 1977.<sup>605</sup> As noted above, the ban was reinstated prospectively in March 1978.<sup>606</sup>

598. *Id.* at 18,115-16.

599. *CPSC VC Aerosol Ban*, *supra* note 553, at 30,112-14.

600. *Id.* at 30,114.

601. *Id.*

602. *CPSC Ruling on Objection to VC Recall*, *supra* note 585, at 36,576-77. In addition to the above objections, the manufacturers alleged that CPSC was required to file an environmental impact statement under the National Environmental Policy Act. *Id.* at 36,577.

603. *Id.*

604. *Id.* at 36,578.

605. *Pactra Indus., Inc. v. CPSC*, 555 F.2d 677, 684 (9th Cir. 1977). Decision on the main issue of the case, the propriety of CPSC's denial of a hearing, was delayed by the drawn-out disposition of a NEPA claim. In December 1974, the court stayed the recall order until CPSC prepared an EIS or, as required by NEPA, submitted a declaration that the recall was not a "major federal action" subject to the EIS requirement. *Pactra Indus., Inc. v. CPSC*, No. 74-2902 (9th Cir., Dec. 15, 1974) (order staying recall until compliance with NEPA). In September, 1975, nine months later, CPSC stated that no EIS was needed and reaffirmed the recall order. *CPSC VC Environmental Assessment*, *supra* note 551. In November, the court lifted the stay and reinstated the recall order. *Pactra Indus., Inc. v. CPSC*, No. 74-2902 (9th Cir., Nov. 6, 1975) (order lifting stay). Somewhat redundantly, in February, 1976 the agency reaffirmed that the recall was in effect. CPSC, *Self-Pressurized Household Substances Containing Vinyl Chloride, Notice of Court Order Affecting Repurchase Requirements*, 41 Fed. Reg. 5425 (1976). At this point it was highly unlikely that there were cans still about.

606. *CPSC Reinstatement of VC Aerosol Ban*, *supra* note 555.

#### 4 Evaluating the Aerosol Regulations

The three agencies' decisions to act promptly were justified by the hazard posed by the use of VC as a propellant. Although that use had ended in early 1974 for economic reasons, prospective bans were needed to assure that VC-propelled products were not reintroduced. The recalls were justified in light of the possibility that even short-term exposures were a cancer hazard and in light of the relatively low expense involved in an effort to retrieve existing stocks.<sup>607</sup>

As noted above, regulation of VC's use as a propellant did not bring out the potential for jurisdictional conflict between the three agencies. Because of the one-sided nature of the balance of risks and benefits in this case, each of the statutes called for the same result, regardless of the differences in their burdens of proof and other substantive criteria. Consequently, no manufacturer had reason to hope that its product would fall under a more lenient provision, and so had no incentive to argue that a particular product, such as a disinfectant spray, was a household product subject to FHSA rather than a pesticide subject to FEPCA, or that another product, such as a breath spray, was a cosmetic subject to the 1938 provisions of FDCA rather than a drug subject to the New Drug Amendments. No consumer group, hoping to call into play the more stringent statute, had an incentive to argue the reverse. In addition, because the decisions were not difficult or controversial, no agency had an incentive to avoid taking responsibility. The potential for jurisdictional conflict exists, however, and there are products over which such conflicts have occurred.<sup>608</sup>

607. The three agencies' success in this context should not obscure other failures. Although they acted quickly with regard to aerosols, they did not take steps at the same time to control the other uses of VC under their jurisdictions. When FDA proposed its aerosol ban, it requested information on migration of VC from PVC packaging into foods, drugs, and cosmetics. *FDA Proposed VC Aerosol Ban*, *supra* note 551, at 14, 121; FDA, *Human Drugs Containing Vinyl Chloride or Packaged in Polyvinyl Chloride Containers. Notice to Drug Manufacturers, Packers, and Distributors*, 39 Fed. Reg. 14,238 (1974). FDA's only subsequent action on these uses was the October, 1975 proposal regarding food packaging; the agency has neither finalized this proposal nor followed up its call for information on drug and cosmetic packaging. EPA delayed promulgation of a hazardous air pollutant standard until October, 1976. CPSC has not even investigated the extent to which household items made from PVC may be a source of VC exposure. The agencies' rapid action on VC's aerosol uses makes more apparent their delay in acting on the other sources of exposure. See text accompanying notes 425-437, 514-533 *supra*, and 772-795 *infra*.

608. An example of a product over which there have been such conflicts, although not under these laws, is the sunlamp. There has been a dispute over when a sunlamp is subject to the 1976 Medical Device Amendments to FDCA, codified in scattered sections of 21 U.S.C. §§ 301-360k (West Supp. 1978), and when it is subject to the 1972 Consumer Product Safety Act, 15 U.S.C. §§ 2051-2081 (Supp. V 1975). Personal communication with Judy Pitcher, *supra* note 551.

Even when divided control over such products does not lead to jurisdictional conflict and inconsistent regulations, it does result in a duplication of effort. There is some value in having three independent inquiries into essentially identical facts; it is less likely that analytical mistakes will go undetected. Nonetheless, considering the backlog of other toxic substances meriting these agencies' attention, it is probable that there are better uses for administrative resources than to double- and triple-check decision making for one substance.

The agencies' experience with VC appears to have led them to this conclusion. In their subsequent actions to control fluorocarbons, another aerosol propellant, the agencies have acted together.<sup>609</sup> Along with OSHA, the three agencies have also established an official liaison among themselves through which to share information and coordinate action on chemicals coming under the jurisdiction of more than one of them.<sup>610</sup> That effort is discussed below.<sup>611</sup>

#### F. Emissions from Transportation of VC—Four Transportation Statutes and the Occupational Safety and Health Act

##### 1. The Key Issues Regarding VC Transportation

The release of VC and other toxic substances while in transit may be a major source of risk for transportation workers and the general public.<sup>612</sup> The history of VC spills and other accidents has been discussed above.<sup>613</sup> Despite the need for at least an investigation of the extent of the hazard and the desirability of controls on this source of exposure, there has been little study and little regulation of the cancer hazard from VC transportation.<sup>614</sup>

609. For a discussion of the agencies' coordinated action on fluorocarbons, see text accompanying notes 842-849 *infra*.

610. See IRLO Agreement, *supra* note 538.

611. See text accompanying notes 851-868 *infra*.

612. Rail, trucking, and vessel shippers and carriers are required to report release of hazardous materials to the Department of Transportation. 49 C.F.R. §§ 171.15-.16 (1976) (rail and trucking reporting); *Id.* § 176.48 (vessel reporting). In 1974, 8,500 hazardous materials accidents were reported to DOT, which has stated that "only a small portion of reportable incidents are actually reported." U.S. Dep't of Transp., *Hazardous Materials Incidents Reports Received During 1974*, at 1 (May 7, 1975). One EPA official expects the number of actual spills to double from a current 1,700 per year "to (at least) 3,000 spills per year by 1980 before leveling off." *Toxic Materials News in Brief*, 5 TOXIC MATERIALS NEWS 104, 105 (1978). Without accurate statistics on release, possible epidemiological connections between accidents and illnesses will remain almost impossible to draw.

613. See text accompanying notes 158-160 *supra*.

614. No epidemiological studies of the effects of VC on transportation workers have been reported. No estimates have been made of the number of people who may be exposed to VC by accidents, nor of the doses they may receive. While some attempts have been made to relate VC emissions from factories to cancer and birth defect rates in nearby communities, there has been no attempt to determine what portion of the so-called "background" level of angiosarcoma of the liver may be connected to the release of VC in transportation. Personal communica-