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January 23, 1989

The Food and Drug Administration
The Dockets Management Branch (HFA-305)
5600 Fishers Lane
Room 4-62
Rockville, Maryland 20857

Dear Sir or Madam:

On behalf of the Society of the Plastics Industry, Inc. (SPI) and its Vinyl Institute, we enclose for filing written comments on the Food and Drug Administration's (FDA) Notice of Intent to prepare an Environmental Impact Statement on its proposed rule providing for the safe use of vinyl chloride polymers in contact with food. 53 Fed. Reg. 47264 (Nov. 22, 1988).

If you should have any questions, or if we can be of any additional assistance, please do not hesitate to contact us.

Very truly yours,

Jerome H. Heckman/PD

Jerome H. Heckman
General Counsel
The Society of the
Plastics Industry, Inc.

Enclosure

cc: Richard J. Ronk
L. Robert Lake, Esq.
Buzz L. Hoffmann, Ph.D.

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Comments of the Society of the Plastics Industry, Inc. on FDA's Notice of Int nt t Prepare EIS in PVC Rulemaking

Docket No. 84N-0334

On November 22, 1988, the Food and Drug Administration (FDA) announced its intention to prepare an Environmental Impact Statement (EIS) on its proposal to provide for the safe use of vinyl chloride polymers in contact with food. 53 Fed. Reg. 47264 (Nov. 22, 1988). Based on the limited impact this proposal will have on the nation's solid waste situation and our belief that FDA already has the most current available information on the environmental issues it has raised, the Society of the Plastics Industry, Inc. (SPI) and its Vinyl Institute1/ continue to believe that the conclusions in the Agency's February 3, 1986 "Finding of No Significant Impact" remain valid and should be reaffirmed without undue delay. At the same time, the Society is anxious to be of help to FDA on any issues properly under consideration.

1/ SPI, the major national trade association of the plastics industry, is a corporation organized under the Not-for-Profit Corporation Law of the State of New York. Its 2,000 member companies and individuals and 49 operating units include those who supply raw materials; process or manufacture plastics or plastics products; and engineer or construct molds or similar accessory equipment for the plastics industry. The majority of SPI members are the processors and converters of plastic resins into end products which represent 75% of the dollar volume sale of plastics in this country. Members of the Vinyl Institute include Air Products & Chemicals, the BFGoodrich Chemical Group, Borden Chemical, Certain-Teed, Dow Chemical U.S.A., Occidental Chemical, PPG Industries, Shintech and VISTA Chemical. Members of the Vinyl Institute account for approximately 82% of the domestic production of vinyl chloride and 85% of the domestic production of polyvinyl chloride.

Of great concern to SPI (and a principal reason for these comments) is our perception that FDA is overreaching in the approach it is now taking toward the environmental review of indirect food additive proposals. In so doing it is making an inappropriate and unjustified attempt to inject itself into the national policy debate on solid waste management alternatives.2/ We respectfully submit that FDA should not arrogate to itself the power and responsibility for dictating solutions to the nation's varied and complex solid waste problems that even now continue to challenge solid waste experts in our state and federal legislatures and environmental agencies where these questions are more properly addressed. Likewise, it should not reach out beyond its assigned task of conducting environmental reviews of food additive petitions and the immediate consequences of regulating an additive substance.

The importance of the Agency's limiting itself to scientific evaluations of whether or not a new food additive will have adverse public health consequences is well demonstrated in this very case. For example, a critical point

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2/ As part of this ongoing debate, the Environmental Protection Agency's Office of Solid Waste is expected to submit a Report to Congress on plastics and plastics recycling in June 1989.

here is that this rulemaking relates to the use of a material employed in only 1-2 percent of all food packaging, a very small portion of the solid waste universe. In fact, PVC packaging of all types constitutes only about one-half of one percent of the municipal solid waste (MSW) stream. While it is unclear what FDA will achieve in this EIS process, it is clear that FDA's final decision in this rulemaking will have no significant impact - for better or for worse - on the country's overall solid waste disposal problems.

SPI, therefore, takes the position that (1) FDA was correct in its initial determination that this rulemaking will have no significant environmental impact and an EIS is not necessary; (2) during the last two years, FDA has already identified and fully examined all of the potential environmental issues that are relevant to this rulemaking and has obtained the most current scientific information available on these issues; (3) the Center for Food Safety's Environmental Impact Section has already gone far beyond its proper sphere in examining the environmental impact of this proposal and should limit its evaluation to those issues that have been the subject of debate in this rulemaking for the past two years; (4) FDA's Notice of Intent and accompanying materials contain only speculations regarding the role of PVC in municipal waste

incineration and recycling programs but offer no new technical information; and (5) FDA's evaluation of these issues cannot be based upon a preference for one solid waste disposal method over another since such policy decisions are squarely within the province of elected officials on the federal, state, and local levels.

In the comments below, we address several of these issues in more detail. Specifically, we (1) urge that the work done by FDA up to now be fully incorporated into the formal EIS process to avoid duplication of effort; (2) identify briefly for the record those areas where FDA's preliminary conclusions are erroneous or premature; and (3) oppose any effort by FDA to involve itself in strictly political questions regarding the efficacy or desirability of particular waste disposal methods.

A. FDA HAS ALREADY IDENTIFIED AND EXTENSIVELY EXAMINED THE ENVIRONMENTAL ISSUES TO BE ADDRESSED BY THE EIS.

During the past two years, FDA has thoroughly examined the environmental issues raised by the Environmental Protection Agency (EPA) in 1986. In fact, it has already completed much of the work that will be needed to prepare an EIS. First, with EPA's help, FDA has identified those environmental issues that it believes are fairly raised by this rulemaking. Second, it

has actively sought and acquired the most current practical and scientific information available on these environmental issues from industry, environmental groups, state and federal environmental officials, and other interested parties. Finally, with the benefit of the views and information provided by these parties and members of the general public in the hundreds of comments it received on this matter, FDA has further refined the relevant environmental issues for evaluation.

FDA has, in essence, already conducted a "scoping" of the environmental issues to be evaluated in the EIS, as required by the National Environmental Policy Act (NEPA) and the regulations of the Council on Environmental Quality (CEQ). See 40 C.F.R. § 1501.7. Thus, very little time should be spent trying to further refine these issues. Instead, FDA should begin to focus on those issues that have been previously identified and refined for analysis, and seek whatever additional information is available, if any, on these issues.

If additional scientific information is availabl , FDA should promptly analyze that information and, if it is reliable, draw conclusions from this evidence regarding the rule's potential environmental impacts. If, on the other hand,

the scientific data and evidence do not exist or are insufficient to permit the Agency to arrive at definitive conclusions on these impacts, FDA need not attempt to resolve all of the remaining "uncertainties" before moving forward with a final rule. As provided by the CEQ rules, when the "information relevant to reasonably foreseeable significant adverse impacts" is incomplete or unavailable because "the overall costs of obtaining it are exorbitant or the means to obtain it are not known," the Agency may simply acknowledge that fact and make the best assessment possible, using whatever credible scientific evidence is available and scientifically-accepted research methods. 40 C.F.R. § 1502.22(b). Significantly, the rules define "reasonably foreseeable" impacts as including remote but very serious (i.e., "catastrophic") environmental consequences, but only if "the analysis of the impacts is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason." Id.

There are certain issues that the Agency has identified that will continue to be the subject of debate for many years to come. Until much more study is done at great cost, the information necessary to resolve these solid waste disposal issues must be considered incomplete and unavailable. As will

be shown below, without such information, FDA's preliminary conclusions are based on pure speculation and conjecture. Given the limited impact of this rulemaking on the overall solid waste situation, this proposal should not be delayed indefinitely while these larger solid waste disposal issues are resolved. It is sufficient that FDA properly weigh the real and potential environmental impacts, as well as any remaining uncertainties in this area, before making its final decision.

In response to specific requests from FDA, SPI will continue to assist the Agency in obtaining the most current information on these issues. With the information it has already obtained, and the additional information provided in comments on its Notice of Intent, FDA is again likely to have in its possession the very latest information available on these issues. It should, therefore, be well on its way to (1) reaching final determinations on the rule's environmental impacts where possible and (2) identifying those issues which cannot yet be resolved by current scientific information.

B. FDA'S PRELIMINARY FINDINGS ARE NOT SUPPORTED BY SCIENTIFIC EVIDENCE.

The Agency's Notice of Intent and Appendix C of its February 2, 1988 letter to EPA contain unsupported, speculative conclusions regarding the role of PVC in the production of

hazardous air contaminants during MSW incineration and its impact on plastics recycling programs. In addition to the comments below, and to ensure that FDA's record is complete, we are also submitting the report that the Vinyl Institute previously submitted to three different EPA offices on the environmental issues raised in this rulemaking. See Vinyl Institute, "Environmental Issues Associated with the Disposal of PVC in MSW" (June 20, 1988).

1. Incineration Issues

FDA continues to overstate the significance of the contribution of PVC to the production of dioxins and furans during the incineration of municipal solid waste and to the corrosion of incineration facilities. With regard to dioxins and furans, SPI does not dispute that the burning of PVC or other chlorinated organics can produce dioxins and furans under poor combustion conditions, such as those in laboratory-scale studies or uncontrolled burning situations. On the other hand, it remains quite clear that the presence of PVC in the MSW stream will have no measurable impact on the level of dioxins/furans actually emitted into the air from properly operated MSW incinerators.

To the extent that FDA relies on laboratory studies in assessing the impact of PVC under actual incineration conditions, its conclusions are not valid. While laboratory-scale incineration studies provide some useful information, these studies frequently employ small samples and use combustion devices designed to produce incomplete or poor combustion conditions. Findings from these studies are largely dependent on the apparatus and conditions employed, and are therefore unrealistic and not representative of the conditions in actual, large-scale incineration facilities. Of the data available in this area, therefore, those obtained from testing at full-scale facilities provide the only realistic information.

As we pointed out over two years ago, there is no evidence in the scientific literature to support the theory that dioxin/furan levels are directly dependent upon the level of chlorine contributed by chlorinated plastics in the waste stream. Current scientific evidence suggests that there is a limiting factor other than the level of chlorine in the formation of dioxin. Because chlorine is ubiquitous in the waste stream, the level of chlorine contributed by non-plastic refuse alone is far greater than that needed to produce the levels of dioxin typically found in incinerator emissions.

Studies performed on actual municipal incinerators3/ show that changes in the level of chlorine in the waste stream that result from the addition or subtraction of chlorinated plastics will not result in corresponding increases or decreases in the level of dioxin/furan emissions. These studies on actual incinerators also show that, even if all plastics are removed from the waste stream, sufficient chlorine is contributed by other components of the waste stream (e.g., paper, wood products and lawn wastes) to produce levels of dioxin/furan emissions that are no different statistically than when the plastic is present in the waste stream. In sum, incineration of MSW containing chlorinated plastics in properly operated incinerators does not affect dioxin/furan emission levels.

FDA's devaluation of the results of the NYSERDA study conducted on the Pittsfield, Massachusetts incinerator is inexplicable. The study and its conclusions are sound and the report has been peer-reviewed. While the study did not attempt to replicate conditions in existing incinerators throughout the

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3/ Karasek, F.W., Viau, A.C., Guiochon, G., and Gonnord, M.F., "Gas Chromatographic-Mass Spectrometric Study on the Formation of Polychlorinated Dibenzo-p-dioxins and Polychlorobenzenes from Polyvinyl Chloride in a Municipal Incinerator," J. Chrom., 270, p. 227 (1983); New York State Energy Research and Development Authority (NYSERDA), "Results of the Combustion and Emissions Research Project at the Vicon Incinerator Facility in Pittsfield, MA," NYSERDA Report 87-16 (July, 1987).

country,4/ it clearly provides far more useful and reliable data than the laboratory tests relied upon by FDA which bear no relation to actual incinerator conditions. The Pittsfield data not only establish that there is no statistically significant relation between the amount of PVC in the waste and the production of dioxins/furans, they also establish that there is a very clear correlation between poor combustion conditions in the incinerator and the production of dioxins/furans.

The assumed improper operation of some incinerators or the burning of MSW under poor combustion conditions does not provide a rational basis for attempting to limit the amount of PVC in the solid waste stream. Even if there were no PVC in the MSW, such improperly-operated incinerators could not meet current ambient air quality requirements. Regulatory efforts should instead be directed towards improving the operating conditions of such incinerators, either through regulation or by including specific conditions and restrictions in the operating permits for these incinerators. The required use of appropriate emission control equipment, now capable of removing up to 99 percent of dioxins/furans, will ensure that the

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4/ The lower temperatures used in certain runs in the NYSERDA study were chosen not because they were thought to represent proper operating conditions but rather to gain information within the experimental design.

dioxins and furans produced during the incineration process by any chlorine-containing substances in the MSW will not be emitted from the incinerator. In contrast, simply limiting the level of PVC in the MSW is not likely to have any impact on the actual level of dioxins/furans resulting from MSW incineration. Moreover, the whole issue of proper incinerator operation is not a question for FDA, but one for EPA and Congress.

With regard to the production of hydrogen chloride (HCl), FDA significantly overestimates the impact of this rulemaking on the levels of HCl emissions from MSW incinerators. Even assuming FDA's figures on the market impact of this rulemaking are correct, FDA underestimates the HCl removal efficiency of modern pollution control equipment. Even using a removal efficiency of 97%, SPI estimates that the impact on typical HCl levels will be roughly one-third of that predicted by FDA (1 ppm increase vs. 3 ppm increase). See Letter to EPA, Appendix C, at 10.

The Agency's conclusions also assume that its action will take place in a vacuum. When it suggests that the increased use of PVC will cause many existing incinerators to exceed state and federal emission standards for HCl, it assumes that such incinerators operate very close to the emissions

limits and will not be likewise affected by increases in chlorine contributed by the many other chlorinated compounds in the MSW stream. Incinerators operating so close to the limit will eventually be faced with higher chlorine levels from any of these sources. Thus, shifts to more modern and more effective (99 percent removal rates) pollution control equipment are inevitable and will bring HCl emissions comfortably within the levels permitted.

With regard to the claim that the generation of HCl from PVC incineration will cause corrosion of pollution control equipment, there is no positive evidence to support this contention. In fact, the one study relied upon by FDA (see Letter to EPA, Appendix C, at 9) suggests just the opposite. The study by Buekens and Schoeters concluded:

> Although the PVC in refuse forms a potential source of the required Cl^- its presence is by no means essential to experience this form of corrosion, provided a proper boiler design and suitable operating conditions are used. It is also unproven that the presence of PVC materially accelerates the process of corrosion, as it undoubtedly does under ill-chosen conditions. Numerous factors intervene and influence each other; under these circumstances it is impossible to pinpoint the actual contribution of each of them under practical operating conditions.5/

5/ Buekens, A. and Schoeters, J., "Refuse Incineration and PVC," Brussels, June 1986, at p. 13.

The study further found:

> Under certain conditions the plastics fraction may contribute to the formation of organic micropollutants or be responsible for superheater corrosion. Since the mechanisms causing such problems are well known adequate countermeasures are taken to alleviate or altogether avoid such problems.6/

In Europe where the waste stream contains much higher concentrations of PVC, incineration has been ongoing for decades without frequent shutdowns or high maintenance costs resulting from corrosion. In addition, at least one other researcher has concluded that "the amount of hydrogen chloride-generating materials in refuse in the absence of polyvinyl chloride itself is sufficient to initiate this series of reactions [leading to equipment corrosion] and doubling or tripling the amount of polyvinyl chloride in the refuse will not, by itself, cause any more corrosion."7/

6/ Id., at 15 (emphasis added).

7/ Warner, A.J., Parker, C.H., and Baum, B., "Plastics Solid Waste Disposal by Incineration or Landfill," Report of a Research Study Conducted for Manufacturing Chemists Association, Washington, D.C., December, 1971.

2. **Recycling Issues**

FDA's conclusions regarding the negative impact of this rule on recycling programs are also unfounded. Despite the progress made in PVC recycling programs in recent years and the promise of significant future progress in this area in the months ahead, FDA concludes without the least bit of "uncertainty" that the increased use of PVC "would have adverse effects on curbside recycling programs" and "on attempts to recycle mixed plastics because HCl is released at temperatures reached in reprocessing plastics." These conclusions are premature, based entirely on speculation, and are unwarranted in light of the new developments that continue to be made in PVC recycling programs.

PVC already has a proven record of recyclability in Europe. Currently, recycled PVC bottles are being converted into such items as profile extrusions and co-extruded foam core pipe, as well as being mixed with other plastics to form a wood substitute material used in such applications as fencing and landscape timbers. Existing recycling processes are being refined and improved while new processes are being developed to compete with them. The technology for recycling PVC and other plastics is becoming more widespread and sophisticated. As the technological capability to recycle plastic waste becomes more

certain, the focus is now turning toward the development of new and larger markets for recycled plastic products. This experience in Europe demonstrates the feasibility of such programs when there is a sufficient supply of recyclable PVC material.

A number of pilot programs are currently underway in this country that have been designed specifically to demonstrate the feasibility of collecting and recycling post-consumer vinyl containers. Early results have revealed no technical barriers to full-scale programs and this is consistent with the more extensive European experience. Among the programs now in progress are:

1. An active research program sponsored by the Vinyl Institute and other organizations at the Center for Plastics Recycling Research at Rutgers University which is specifically designed to address the processing of PVC commingled waste, and to define suitable use areas and markets for commingled products such as plastic lumber produced in an Advanced Recycling Technology ET-1 extruder;

2. Reclamation of PVC extruded tubes (used for transporting computer chips) at Vermont Republic Industries, St. Albans, Vermont. The recovered tubes are ground and the resultant PVC chips are sold to pipe extruders;

3. Recovering and marketing of reclaimed flexible and rigid PVC from post-

consumer solid waste has been successfully achieved at R2B2 Recycling's plastic recycling division, 1809 Carter Avenue, Bronx, New York 10457. R2B2 (Recoverable Resources/Borough Bronx 2000, Inc.) is a unit of the South Bronx 2000 Local Development Corporation, a non-profit economic development agency, and is nationally recognized for its distinctive vision and unique experience in plastic recycling.

PVC also poses no unusual problems for source separation, i.e., the process of sorting components of municipal solid waste by type of material. Clear vinyl bottles destined for recycling easily can be separated out of the waste stream through simple visual inspection because of their glass-like clarity and gloss, and distinctive mold mark. In addition, a new voluntary container coding system is now being implemented by SPI members that will greatly facilitate container identification and separation. See Attachment A. PVC containers would be separately identified by their own code under this system. Technology has also been developed by Tecoplast in Italy that enables mechanical separation of PVC bottles from polyethylene terephthalate (PET) bottles and research at the Rutgers University Center for Plastics Recycling Research is actively pursuing mechanical separation of mixed plastic containers by a scanning/sorting technique.

With regard to the supposed adverse impact of PVC on commingled plastics recycling programs, PVC bottles not source separated and composite plastic bottles containing a layer of PVC can easily be accommodated in a commingled plastics program. As SPI has shown in its January 13, 1987 comments and subsequent submissions, some recycling programs can accommodate up to 50% PVC in their commingled material. The level of PVC in the mix is necessarily a decision for the recycler itself to make. Such experimentation on a local level can lead to new advances permitting higher levels of PVC in the material. If a recycler chooses a lower level of PVC, the easily identifiable PVC bottles can be removed from the incoming material leaving only relatively small amounts of PVC contributed by the PVC-containing composites and the few unidentified PVC bottles.

Because PVC recycling efforts (e.g., technology, market development, etc.) are only at their early stages, they must not be judged by the standard set by recycling programs for glass, aluminum, or even PET beverage bottles since programs for these materials have been under development for a far longer time. Rather, the potential for PVC recycling should be judged on the progress that has been made in recent years and months, the existence of fully operational programs in other countries where the amount of recyclable PVC material is

greater, and the continued interest and commitment by industry and researchers in making further progress toward viable PVC recycling programs.

If FDA wishes to speculate, all signs point toward continued progress in the development of economically viable recycling programs for PVC. As FDA points out, PVC recycling is "more practical in France than it is in the U.S. because a sufficiently large supply of incoming used material is essential to any recycling operation and because there is little problem in having to separate different kinds of plastics before recycling." Letter to EPA, Appendix C, at 15. Because SPI's container coding program and successful research to develop mechanical sorting and separating using instrumentation will greatly facilitate the separation of different plastics, the increased use of PVC, whether through normal market growth or through whatever impact FDA's rule may have, can provide a sufficient supply of recyclable PVC in the U.S. to make PVC recycling programs economically viable.

C. DECISIONS ON THE DESIRABILITY AND UTILITY OF SPECIFIC SOLID WASTE DISPOSAL ALTERNATIVES ARE POLITICAL DECISIONS BEST LEFT TO ELECTED OFFICIALS.

The Notice of Intent indicates that FDA intends to focus on the "uncertainties" of PVC's impact on incineration

and recycling. Many of these questions are now being debated on a national level. Their significance goes far beyond the narrow world of FDA's regulation of food packaging materials. FDA certainly does not have the resources to resolve these issues on its own.8/ In dealing with such issues, we submit that it is not appropriate for FDA to attempt to make value judgments regarding the usefulness or desirability of any particular solid waste disposal method. Especially when uncertainties regarding potential local impacts exist, decisions as to what solid waste disposal method is most appropriate for a given state or community is one best left to the elected officials in that jurisdiction. A method that is suitable in one area may be particularly unsuitable in another. A community's elected representatives, working with local solid waste management officials, are those best able to make these value judgments for the people of that locality. For issues having broader national significance, Congress is the appropriate body to be making critical decisions regarding the regulation and promotion of the various disposal alternatives.

8/ The Agency should also keep in mind that these uncertainties, in light of existing evidence, may well be resolved in a manner demonstrating PVC's limited environmental impact.

FDA can adequately fulfill its duties under NEPA without encroaching on the rights of states and localities to decide through their elected officials how best to resolve the remaining issues regarding disposal alternatives that have been identified in this rulemaking. An FDA rulemaking that is intended primarily to protect the public health by ensuring the safety of food packaging materials should not be delayed indefinitely while the Agency attempts to resolve much larger environmental questions that are outside its area of responsibility, and probably its expertise. FDA should reject EPA's attempt to delegate to FDA the responsibility for resolving issues that are clearly within EPA's own jurisdiction and expertise. Having identified and thoroughly evaluated these questions, FDA's NEPA responsibilities will have been fulfilled. The environmental impacts should then be considered and a final rule should issue.

D. Conclusion

Based on the foregoing discussion, we believe that FDA should: (1) limit the scope of its investigation to an objective analysis of the likely environmental consequences of this action, (2) avoid becoming further enmeshed in the national debate on solid waste issues that are beyond the Agency's proper regulatory sphere, (3) reaffirm that there will

be no significant environmental impact, and (4) issue a final rule governing vinyl chloride polymers.

Respectfully submitted,

Jerome H. Heckman PLD

Jerome H. Heckman
General Counsel
The Society of the
Plastics Industry, Inc.

Food and Drug Administration

[Docket No. 84N-0334]

Vinyl Chloride and Other Chlorinated Polymers; Intent To Prepare an Environmental Impact Statement

AGENCY: Food and Drug Administration.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it intends to prepare an environmental impact statement (EIS) on the effects of the proposed amendments to its food additive regulations to provide for the safe use of vinyl chloride polymers in contact with food. The EIS will also consider the potential environmental impact of four food additive petitions involving chlorinated polymers. The EIS will be prepared in accordance with 40 CFR Part 1500, the council on Environmental Quality's (CEQ's) regulations for implementing the procedural provisions of the National Environmental Policy Act (NEPA), and 21 CFR Part 25, FDA's NEPA policies and procedures.

DATE: Comments by January 23, 1989.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Buzz Hoffmann, Center for Food Safety and Applied Nutrition (HFF-304), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0277.

SUPPLEMENTARY INFORMATION:

I. Background

On February 3, 1988, FDA published a proposal to amend its food additive regulations to provide for the safe use of vinyl chloride polymers in contact with

food (51 FR 4177). The term "vinyl chloride polymers" includes both vinyl chloride homopolymer (polyvinyl chloride or PVC) and copolymers of vinyl chloride with other chemicals. The agency proposed to take four actions: (1) To provide for the safe use of certain vinyl chloride polymers by establishing limits on the amount of residual vinyl chloride monomer that they may contain, (2) to codify all known prior sanctions for vinyl chloride polymers, (3) to provide for the use of certain unregulated vinyl chloride polymers in manufacturing vinyl chloride bottles, and (4) to remove vinyl chloride/vinylidene chloride copolymers from the list of materials that may be used as coatings on fresh citrus fruits.

In its notice of proposed rulemaking, FDA announced its conclusions that the proposed action would not have a significant impact on the human environment, and that an EIS was not required. The agency made its environmental assessment (EA) and finding of no significant impact (FONSI) available for public inspection in the Dockets Management Branch (address above).

At that time, FDA requested the submission of any data bearing on the issues and conclusions in the EA and FONSI. The agency specifically requested information on: (1) The environmental fate and effects of di(2-ethylhexyl) phthalate (DEHP), di(2-ethylhexyl) adipate (DEHA), and epoxidized soybean oil (ESO), three plasticizers used in conjunction with vinyl chloride polymers; and (2) whether vinyl chloride polymers contribute to the emission of polychlorinated dibenzo-*p*-dioxins (dioxins) and polychlorinated dibenzofurans (furans) from municipal solid waste (MSW) incinerators. FDA said it would reexamine its conclusions if new information became available suggesting that the proposed action will have a significant environmental impact.

In response to this request for information, FDA received six submissions during the formal comment period that related to environmental issues, five from industry trade associations, and one from the U.S. Environmental Protection Agency (EPA). The industry supported the FONSI and provided environmental data on DEHP and DEHA. The industry submissions also concluded that (1) incineration of vinyl chloride polymers does not contribute to the formation of dioxins and furans, and (2) vinyl chloride polymers do not contribute significantly to acid gas emissions as compared to other sources.

EPA identified no strong reasons for FDA not to proceed with the proposed action but expressed concerns about the two potential environmental problems identified by FDA. EPA said that there was uncertainty about (1) the environmental fate and effects of DEHP, DEHA, and ESO, and (2) the extent to which vinyl chloride polymers contribute to the emission of dioxins and furans from MSW incinerators.

EPA also expressed concern that FDA's EA did not thoroughly support the FONSI and said that FDA should (1) present more clearly the potential effects of the proposed rule on the levels of use and disposal of plasticizers and plastics, (2) expand the discussion mitigation measures, and (3) clarify FDA's decision not to delay action on the proposed rule pending further studies to eliminate the uncertainties on the role of vinyl chloride polymers in emissions of dioxins and furans from MSW incinerators.

Because of EPA's comments, FDA decided to evaluate further its decision not to prepare an EIS and sought additional information. FDA contacted scientists to obtain information about the role of vinyl chloride polymers in the emission of dioxins and furans from MSW incinerators. The agency also contacted State and local government officials to learn what concerns they might have about FDA's action. Subsequently, FDA received about 1,400 comments and inquiries about the environmental impact of the proposed rule after the comment period had closed.

The comments from environmental organizations, State and local government officials, and citizens expressed concern about FDA's proposed action and requested that FDA prepare an EIS. These comments identified four major environmental issues involving the effects of postconsumer disposal of vinyl chloride polymer food-packaging material: Incineration of MSW, recycling of MSW, the solid waste management crisis, and adjuvants used with vinyl chloride polymers. The comments submitted by industry claimed that FDA's proposed action would not have significant environmental effects, and that an EIS was not necessary. These comments also provided information on the issues identified above.

Using the new information, FDA prepared an evaluation of the environmental issues in January 1988 as part of its internal deliberations on the proposed rule. The principal findings were:

(1) FDA's proposed action would result in an estimated increase of 180 million pounds in the annual use of vinyl chloride polymers for food-contact applications by 1991.

(2) FDA's proposed action would have little, if any, effect on emissions of dioxins and furans from incinerators operating under good combustion conditions and with state-of-the-art flue gas controls.

(3) FDA's proposed action would result in increased emissions of hydrogen chloride (HCl) from MSW incinerators, which would increase the cost of emission controls, would increase the amount of scrubber waste, and may affect the ability of incinerator operators to comply with existing or anticipated emissions standards.

(4) FDA's proposed action would not affect stratospheric ozone levels or significantly contribute to the overall acid precipitation problem.

(5) Increased use of vinyl chloride polymer food-packaging materials would have adverse effects on curbside recycling programs to the extent that these materials will compete with food-packaging materials that are being recycled. The impact of FDA's proposed action may become greater over time as the number of curbside recycling programs increases, unless markets are established for recycled vinyl chloride polymers.

(6) Vinyl chloride polymers may have adverse effects on attempts to recycle mixed plastics because HCl is released at temperatures reached in reprocessing plastics.

(7) FDA's proposed action would seem likely to exacerbate the attempts by some State and local authorities to deal with the growing solid waste management crisis. The impact would increase over time as the fractions of MSW that are incinerated and recycled continue to increase.

(8) The increased level of use of vinyl chloride polymers resulting from FDA's proposed rule represents only a 2 percent increase in the total vinyl chloride polymer resin market. However, the impact of FDA's proposed action on the solid waste management crisis is greater than suggested by its effect on the total market. This paradox results from the fact that most vinyl chloride polymer is used for products such as building and construction materials, which are often disposed of by methods other than by incineration and which are not targeted for postconsumer recycling.

(9) FDA's proposed action would result in no more than a small increase in the amounts of the plasticizers DEHP, DEHA, and ESO entering the environment because plasticizers are not used in rigid vinyl chloride polymer

food-packaging materials, the products most affected by the proposed action.

FDA's January 1988 evaluation also identified several matters on which available information is inadequate to support findings about the nature and extent of potential environmental impacts. The major uncertainties include:

(1) The role and importance of vinyl chloride polymers in the formation and emission of dioxins and furans from MSW incinerators under the variety of incineration conditions that exist, particularly from improperly designed or operated incinerators or under transient conditions.

(2) The extent to which increased HCl emissions will increase operating and maintenance costs of MSW incinerators.

(3) The effects of increased HCl emissions on exposed organisms.

(4) The effects of HCl on the mobilization of heavy metals in MSW to fly ash or fumes in incinerators.

(5) The effects on incineration of increased amounts of vinyl chloride polymer bottles containing organotin stabilizers.

On February 2, 1988, FDA requested EPA's assistance in the environmental review of FDA's proposed rule on vinyl chloride polymers and specifically requested EPA's review of FDA's written evaluation of the issues. EPA responded, in a letter dated May 23, 1988, that FDA's analysis and preliminary conclusions fairly and accurately addressed the environmental issues associated with the proposed rule. EPA said that the issues that need to be addressed include: (1) The effect of vinyl chloride polymer incineration on municipal incineration plant compliance with State emission requirements for HCl, (2) complications created in recycling programs as a result of the presence of vinyl chloride polymers, (3) the possibility that increasing use of vinyl chloride polymers will exacerbate the existing solid waste crises associated with diminishing landfill capacity, (4) the effect of vinyl chloride polymer incineration on emission of dioxins and furans from MSW incinerators, and (5) the impact of plasticizers and other adjuvants used in rigid and semirigid vinyl chloride polymer containers. EPA said that several of the significant criteria in the CEQ's regulations (40 CFR 1508.27) are met by the proposed action and recommended that FDA perform a comprehensive EIS. FDA's evaluation and EPA's response are available from the Dockets Management Branch (address above).

II. FDA's Determination on Need for an EIS

In light of FDA's own analysis and EPA's findings and recommendation, FDA has determined that the proposed action may have significant environmental effects, and that an EIS must be prepared in accordance with 21 CFR 25.42.

The proposed rule of February 3, 1988, described FDA's evaluation of the human health risk presented by vinyl chloride monomer from the use of vinyl chloride polymers. The agency concluded that there is a reasonable certainty of no harm from the exposure to vinyl chloride monomer that may result from the use of vinyl chloride polymers in food packaging complying with the vinyl chloride monomer limitations set forth in the proposed rule. The proposed rule included limits on vinyl chloride monomer ranging from 5 to 50 parts per billion by weight of the vinyl chloride copolymer components, depending upon the particular application. These limits were proposed following a quantitative risk assessment by the agency that was based upon consideration of the potential exposure to vinyl chloride monomer and the potency of the monomer as determined by animal bioassays.

The comments on the proposed rule have not provided any basis for FDA to alter its tentative conclusion about the human health risk. Consequently, the agency has no concern about the safety of food that comes in contact with articles that comply with the monomer limits stated in the proposed rule. Therefore, pending development of an EIS and review of the environmental effects of the proposed rule, the agency advises that it will not take action against current uses of vinyl chloride polymers that are in compliance with these limits.

III. Food Additive Petitions Involving Halogenated Polymers

The CEQ regulations require consideration of the cumulative effects of an agency action and other past, present, and reasonably foreseeable future actions (40 CFR 1508.7). In its letter of May 23, 1988, EPA recommended that FDA consider the cumulative effect of vinyl chloride polymers and similar plastic products used in food-packaging materials. Consequently, FDA considered whether five food additive petitions that are before, or have recently been before, the agency and that involve halogenated polymers should be included as part of the environmental review of the proposed rule on vinyl chloride polymers.

FDA has decided not to delay action on two petitions submitted by The Dow Chemical Co. on the use of vinylidene chloride/methyl acrylate copolymers (FAP 6B3938, to increase the temperature for use of the copolymer from 121 °C to 135 °C, and FAP 6B3953, for use of the copolymer in food-packaging systems to be sterilized with hydrogen peroxide). (See 51 FR 29612; August 19, 1986, and 51 FR 35287; October 2, 1986). Elsewhere in this issue of the Federal Register, FDA is publishing final rules that grant these petitions. Because vinylidene chloride copolymer contains chlorine, FDA believes that the presence of this copolymer in the MSW stream may raise the same types of issues as vinyl chloride polymers. However, FDA has concluded that approval of these two petitions would result in a very small increase in the amount of chlorine entering the MSW stream and thus would not have a significant impact on the human environment. Nonetheless, the agency also decided to consider the environmental effects of the use of these copolymers in the EIS that will be prepared for the proposed rule on vinyl chloride polymers. The agency's findings of no significant impact and the petitioner's EA's may be seen at the Dockets Management Branch (address above).

Any new petitions that would result in a substantial increase in the use of vinylidene chloride polymers will be of concern. Such an increase could result from either a single petition or from a number of petitions that individually would produce only a small increase in the use of vinylidene chloride polymers. Under the CEQ regulations, individually minor actions taking place over a period of time can collectively be significant (40 CFR 1508.7).

FDA has under review three food additive petitions that involve halogenated polymers for use in contact with foods, two of which will be considered in the EIS. One petition, FAP 7B3994 (52 FR 21122; June 4, 1987), submitted by The Dow Chemical Co., requests approval of certain vinylidene chloride/vinyl chloride copolymers for use in food-packaging systems to be sterilized with hydrogen peroxide. The second petition, FAP 7B3985 (52 FR 12999; April 20, 1987), submitted by the Union Carbide Corp., is for use of vinyl chloride-acetate hydroxyl-modified copolymer, reacted with styrene-maleic anhydride copolymer, as a coating of articles intended for use in contact with food.

These two petitions would collectively increase the use and disposal of vinyl chloride polymer food-packaging material. Therefore, the issues that need to be addressed for these petitions are essentially the same as the issues that are to be addressed in the EIS for FDA's proposed rule. Considered together, these petitions would produce a substantial net increase in the amount of chlorine entering the MSW stream over and above the increase predicted as a result of FDA's proposed rule. Most of this increase would be contributed by the vinylidene chloride component of the copolymer in FAP 7B3994. FDA will delay action on FAP 7B3994 pending completion of the EIS process. However, FDA does not intend to delay action on FAP 7B3985 on environmental grounds. FAP 7B3985 concerns a copolymer that is expected to replace currently-used solvent-borne chlorinated polymers that have a higher chlorine content. Consequently, this action would result in a small net decrease in the chlorine entering the MSW stream.

FDA has decided not to consider in the EIS the environmental impact of FAP 7B4040 (52 FR 42728; November 6, 1987), submitted by Ausimont USA, Inc., for use of an ethylene/chlorotrifluoroethylene copolymer in repeat-use applications in contact with food. FAP 7B4040 concerns a copolymer that will be used in food-processing plants as piping to carry various foods, including hot water. In contrast to disposable food-packaging materials, this type of product is likely to be disposed of by methods other than incineration, such as special landfills. Consequently, any environmental impact associated with incineration of this halogenated polymer would be averted.

IV. Alternatives

Alternatives that will be considered in the EIS include: (1) Taking no action (i.e., withdrawing the proposed rule and denying the petitions), (2) deferring action until still more experimental work is done to determine the role of vinyl chloride polymers in MSW incinerator emissions of dioxins and furans under representative conditions and to address other uncertainties, (3) making final FDA's September 3, 1975, proposed rule to prohibit some uses of vinyl chloride polymers (40 FR 40529), and (4) making final FDA's 1988 proposed rule, except requiring that vinyl chloride polymer food containers be labeled to facilitate the separation of vinyl chloride food packaging from other wastes that are to be incinerated and recycled. Other reasonable alternatives that are submitted by interested parties will also be considered.

V. Scoping Process And Request For Comment

The purpose of the scoping process is to determine the scope of issues to be addressed in an EIS and to identify the significant issues related to a proposed action (40 CFR 1501.7). FDA has tentatively decided not to hold a scoping meeting for the EIS. The issues that will be addressed in the EIS have been adequately identified in (1) the previously prepared EA and FONSI, (2) the comments the agency has received, (3) FDA's recent written evaluation of the issues, and (4) this notice of intent. However, to ensure that the full range of environmental issues related to the proposed actions is addressed, and that all significant issues are identified, FDA is requesting additional comments, suggestions, and information from all interested parties.

FDA is particularly interested in information that (1) would support or refute FDA's current understanding of the impact of these proposals or that would eliminate the existing uncertainties, (2) suggests alternative actions that the agency might consider, particularly ones that would mitigate some or all of the potential environmental impacts, and (3) would provide a basis on which to establish the costs and benefits of requiring a label to facilitate source separation of vinyl chloride polymer food containers. To be of most use to the agency, information and comments should be fully supported and referenced.

Written comments and information concerning the proposed actions and the EIS should be submitted to the Dockets Management Branch (address above) by January 23, 1989.

Dated: November 14, 1988.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

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