ADVISORY OPINION #279

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U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

October 9, 1980

OFFICE OF THE
GENERAL COUNSEL

Peter G. Beeson, Esq.
U.S. Department of Justice
Environmental Enforcement Section
Washington, D.C. 20530

Dear Mr. Beeson:

This is in response to your request that we review Plaintiff's Motion for Summary Judgment in GPS Industries, et al. v. Environmental Protection Agency, No. 80-1163, D.C.D.C., and provide you with our views on allegations in the motion that the special packaging standards for pesticides established by the Environmental Protection Agency under Section 25(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136w(c)(3), are inconsistent with similar standards established by the Consumer Product Safety Commission and its predecessor the Food and Drug Administration under the Poison Prevention Packaging Act of 1970 (PPPA), 15 U.S.C. 1471 et seq. You further requested that we furnish you with our interpretation of the meaning of the terms "technically feasible, practicable, and appropriate" contained in Section 3(a)(2) of the PPPA, 15 U.S.C. 1472(a)(2), as they relate to the issue of whether the PPPA requires that child-resistant packaging which is adaptable to existing manufacturers' containers and packaging lines be readily available before the Commission can promulgate a standard under the Act.

The Consumer Product Safety Commission is charged, pursuant to Section 30(a) of the Consumer Product Safety Act, 15 U.S.C. 2079(a), with administration and enforcement of the Poison Prevention Packaging Act. The latter authorizes the Commission to establish standards requiring child-resistant packaging for certain substances which present a threat of accidental injury to young children. Basically, the Act requires that four elements be considered in establishing a standard. First, the substance to be regulated must be a household substance. Second, the substance must present a risk of serious injury or serious illness to children

under five years of age who might handle or accidentally ingest it. Third, the hazard must arise because the substance is accessible to such children through or as a result of its packaging. Fourth, packaging which would prevent or restrict such access must be technically feasible, practicable, and appropriate.

The jurisdictional authority to regulate chemical products under the PPPA is extremely broad. The Act authorizes the Commission to establish standards for substances used in or around the household which are foods, drugs, cosmetics, or "hazardous substances." The term "hazardous substance" is defined as any substance which is toxic, corrosive, an irritant, a strong sensitizer, flammable, or which generates pressure by decomposition, heat, or other means, if such substance may cause substantial personal injury or illness as a result of handling or use, including reasonably foreseeable ingestion by children. See Section 2(f)(1) of the Federal Hazardous Substances Act, 15 U.S.C. 1261(f)(1). The legislative history of the PPPA indicates that Congress, by defining the scope of jurisdiction in this fashion, intended to give the Commission considerable latitude in determining what substances or classes of substances to regulate. Thus, the House Report based its findings of need for the legislation, in part, on data showing that the principal products involved in 1968 national poisoning accident data were cleaning and polishing agents, cosmetics, pesticides, turpentine and related paint products, and drugs and medicines (House Report No. 91-1642, 91st Cong., 2d Sess. (1970), at 5). Each of these is a broad category which includes a variety of products which differ in content and/or intended use. Similarly, the Senate Report, in its discussion of the meaning of the term "substance," stated:

> The term "substance" rather than "products" was used in order to avoid possible ambiguity. "Substance" is a broader term than "product" and the Secretary [now the Commission by virtue of the 1972 transfer of functions from the Food and Drug Administration to the Commission] will be free to define the specific reference of the term in each case according to the nature of the substance and the hazard involved. The Commission intended broad reference in order to include all substances likely to be found in or around the home. . . Senate Report No. 91-845, 91st Cong., 2d Sess. (1970) at 9.

The Senate Report also recognized that, by regulating broad categories of substances, certain subcategories which did not necessarily present a risk of injury to young children might be subject to a special standard and accordingly

included a provision in the statute which specifically authorized the Commission to exempt such subcategories. Senate Report No. 91-845, supra, at 7 and 11. Although the exemption provision was stricken from the final version of the PPPA, this approach to regulation was endorsed by both Houses of Congress in the Conference Report. House of Representatives Report No. 91-1755, 91st Cong. 2d Sess. (1970) at 8.

Given this mandate, we have consistently regulated, on a generic basis, chemical substances with demonstrable potential for injury which are also customarily packaged in containers which make those substances accessible to children.1/ While ingestion data has been cited in support of regulating each substance, that data has not controlled the decision whether to regulate. Rather, ingestion data is one of many types of information to consider, including toxicological and other human experience data, to determine whether special packaging is necessary.2/

We believe that this type of approach, rather than one which would permit the Commission to regulate specific products or product categories only when substantial ingestion data already exists to demonstrate that those products have been involved in childhood poisonings, is consistent with the objectives of Congress. This approach further takes into account the epidemiology of accidental ingestions and other types of incidents involving young children reported yearly to the National Clearinghouse for Poison Control Centers (NCPCC).

1/ In three cases involving petroleum distillates, the agency restricted its rule to products intended for specific purposes--furniture polishes, paint solvents, and illuminating and kindling preparations. In part this approach was based on specific references in the legislative history which indicated that Congress specifically intended these products to be regulated under the Act. See Senate Report 91-845, supra, at 2 and House Report 91-1642, supra, at 5. In addition, however, these products warranted special consideration on the basis of intended use because they are often ingested while being used--a circumstance which special packaging would not address. See 38 FR 2757, 37 FR 5613, and 41 FR 16946. The Commission is currently considering a rule which would generically regulate all other similar petroleum distillate products.

2/ See, e.g., 37 FR 7809 in which the sole incident data indicated that over a 5-year period, sulfuric acid had been involved in 10 severe external burn injuries, one of which resulted in death.

The NCPCC publishes a yearly compilation of data voluntarily submitted from over 500 poison control centers nationally. This compilation in part lists incidents involving specific trade name products or narrow product categories determined by product use. The NCPCC data reveals that virtually every product stored or used in or around the homes has the potential to be ingested. For example, the 1978 compilation of data listed reports involving over 93,000 ingestions of potentially harmful products. However, while reported incidents involving a specific trade name product or a narrow product category may be few,3/ the substance involved in these reported incidents may be also present in a variety of other trade name products or product categories. The true picture of the potential of that substance to cause injury to children therefore depends on the number of the products in which it is found. For example, methyl alcohol is used as a solvent in a large number of products. A rule requiring special packaging for windshield washer antifreeze containing methanol would ignore the fact that carburetor cleaners containing methanol are also packaged and marketed in a fashion which make them equally susceptible to ingestion by young children in the home. We generally take this into account in our regulatory approach by combining data on trade name products containing a specific hazardous chemical substance into one broad category which provides an overview of the contribution of the substance contained in each of those products to the overall ingestion problem. This broad category often forms the basis for our rulemaking. We therefore support our regulations by reference to human experience and ingestion data on the broad product category rather then on trade name products or categories narrowly drawn on the basis of product use.

We recognize that, to cause injury, a substance must be present in a toxic or harmful amount. Accordingly, each rule requiring special packaging for a non-drug chemical substance has established a level below which the product containing that substance are not subject to the rule. These levels duplicate levels at which cautionary labeling under the Federal Hazardous Substances Act (FHSA) warning against accidental ingestion, and, in the case of corrosive

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3/ We would note that the absence of ingestion data is not necessarily indicative of the safety of a product. Rather such absence may relate to the low market share of the product, the limited number of units produced, or inadequacies in incident reporting systems.

products, contact with skin or eyes is required.4/ As a prerequisite to requiring such labeling under the FHSA, a substance must be shown to be toxic and/or corrosive and to have the potential to cause substantial injury or illness during or as a result of any customary or reasonably foreseeable handling or use including reasonably foreseeable ingestion by children. The determination of whether cautionary labeling warning against ingestion or skin or eye contact is necessary rests on animal studies, human experience data, and expert medical and toxicological opinion. Accordingly, the requirement for cautionary labeling of a product containing a hazardous substance at a given concentration is also an accurate indication of the hazard presented by the substance in that concentration to young children.5/

As stated before, our special packaging regulations for products containing hazardous substances generally cover generic chemicals which present a risk of serious injury to young children. This is not, however, the sole method in which special packaging regulations have been adopted. Rather, we believe that, to regulate, there need only be an identifiable category of products with a demonstrable potential

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4/ See, for example, 16 C.F.R. 1500.14 which requires, on the basis of human experience data and expert opinion, that products containing ethylene glycol, petroleum distillates, or turpentine in concentrations of 10% or more bear the statement "Harmful or fatal if swallowed" and products containing methanol in concentrations of 4% or more bear the statement "May be fatal or cause blindness if swallowed." These substances are regulated at identical levels under the PPPA.

5/ Note also that products required to be so labeled must bear the statement "Keep out of reach of children" in recognition of the hazard to young children.

for injury to young children.[6/] Thus, the Food and Drug Administration, (FDA) when it was charged with administration of the PPPA, regulated human oral prescription drugs and controlled drugs, categories of products which include many different chemical substances and which had been implicated in thousands of accidental ingestions. Similarly, when FDA proposed to regulate pesticides (37 FR 18629), it did not do so on a chemical by chemical basis. Rather, it based its regulation on human experience data and laboratory tests on animals demonstrating that many pesticides present a threat of serious injury or illness to young children, and on data from the NCPCC indicating that pesticides have been widely involved in accidental ingestions and injuries to children. It further restricted the scope of the regulation to pesticides exhibiting levels of toxicity for which cautionary labeling was required under the FIFRA and its implementing regulations, 40 C.F.R. Part 162. We understand that an identical approach was followed by EPA in establishing its special packaging regulations for pesticides, 44 FR 13019.

We believe that this approach is entirely consistent with the regulations our agency has issued. For example, just as the Commission regulation covering paint solvents, 41 FR 16945, delineates a product category in terms of its use, so the FDA proposal and EPA regulations covering pesticides

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6/ It is worth noting here that each of the statutes administered by the Commission establishes its own criteria for the nature and degree of hazard which must be present in order for the agency to regulate. Thus, the FHSA requires a showing of a risk of "substantial injury or substantial illness," the PPPA covers products which present a threat of "serious personal injury or serious illness," while the Consumer Product Safety Act (CPSA) addresses "unreasonable risk(s) of injury." The types and amounts of information which the Commission must consider in regulating products under each of the respective statutes can also vary considerably. Accordingly, we do not believe that the statutory language of or precedents established under the CPSA, for example, are necessarily applicable to or appropriate for regulations or actions under either of the other statutes. Specifically, we do not believe that the PPPA, for example, requires the Commission to establish that there is an "unreasonable risk of injury" before proceeding to regulate under that Act, nor are we of the opinion that the PPPA requires the Commission to make the findings that would be required for the Commission to issue a consumer product safety rule under Section 9 of the CPSA. We would also note that, even under the balancing test for determining unreasonable risk contemplated by the CPSA, the Commission is not required to demonstrate proof of actual injuries attributable to a product before the Commission can regulate a product under the CPSA. See Senate Report 92-749, supra, at 15 and 27.

categorize products by intended use--preventing, destroying, repelling or mitigating pests, or regulating, defoliating, or dessicating plants. Just as the concentrations at which paint solvents requiring special packaging contain benzene, toluene, xylene and petroleum distilates are the same levels at which cautionary labeling is required under the FHSA to warn of the potential danger associated with accidental ingestion, so the EPA pesticide special packaging regulation is limited to pesticides requiring cautionary labeling under FIFRA. The FDA pesticide proposal, the EPA final order regulating pesticides, and the Commission paint solvent regulation are all based on widespread toxicological and human experience data, including ingestion data, indicating that these types of products presented a clearcut threat to young children. Finally, although unlike the Commission's paint solvent standard neither the FDA pesticide proposal nor the EPA regulation identify specific chemical compounds subject to the regulation, both covered a variety of products of demonstrable toxicity which have been involved in childhood injury. This, of course, is similar to the approach taken by the FDA in regulating human oral prescription and controlled drugs.

As stated earlier, in addition to demonstrating potential for injury by toxicological data, injury information, expert medical opinion or other scientific means, we must also show that special packaging is technically feasible, practicable, and appropriate. A finding of "technical feasibility" requires that technology exists to produce packaging which meets the standards for child-resistance. To be "practicable," a special package must be susceptible to modern mass production and assembly line techniques. A finding of "appropriateness" requires that special packaging not be detrimental to the integrity of the substance to be regulated or interfere with its storage or use. Senate Report 91-845, supra, at 10.

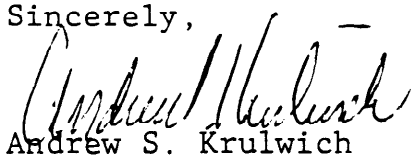
On several occasions, commenters on regulations proposed by the FDA and the Commission challenged the technical feasibility, practicability and appropriateness of special packaging for the substances to be regulated on the basis that special packaging adaptable to their existing containers or packaging equipment was not available. Specifically, this issue was raised with respect to 43 mm. threaded child-resistant closures in 1972 when we published a final order covering products containing lye. See 37 FR 21635. We, and the FDA before us, have consistently taken the position that the findings required by the statute do not require that special packaging be immediately available and lend itself conveniently to the existing packaging and packaging equipment of each manufacturer of a product subject to a regulation. Rather, the PPPA contemplates a change in packaging and provides a delayed effective date for each standard of

at least 6 months to allow manufacturers to make such a change, 15 U.S.C. 1471. See 37 FR 21635, 38 FR 33280-33281, 41 FR 22266, 38 FR 2758, 41 FR 16947. The rationale for this position is clear. Were we required to wait until child-resistant packaging adaptable to every existing container was in production before we could promulgate a standard for a substance, manufacturers could simply prevent the regulation from ever going into effect by inaction.

In order to make special packaging available on the market, a considerable capital investment is necessary to acquire tooling to produce the packaging. Absent some assurance that there will be a return on that investment, packaging manufacturers are reluctant to take the necessary steps to go into production. To date, that assurance has been provided by the fact that special packaging standards have required manufacturers to convert to child-resistant packaging by a specified date to comply with the law. Were, however, special packaging regulations conditioned on the immediate availability of special packaging adaptable to existing containers and packaging lines, the only stimulus for the packaging industry to invest and "tool up" would be voluntary commitments from manufacturers to purchase the finished product. Thus, manufacturers could completely avoid regulation by simply continuing their current packaging practices and refusing to order child-resistant packaging. This would be especially true for small volume items like the 43 millimeter threaded closure where the expected purchases would be insufficient to amortize the capital investment necessary to manufacture a child-resistant closure of that size. Note that in the eight years since the 43 millimeter closure issue was first raised, no one has had sufficient impetus to design and produce a child-resistant closure of that diameter. Accordingly, we have denied claims for relief or extension of time based on claims that special packaging is not adaptable to existing containers when alternate technology has been available and adequate time has been allowed to order and convert to new packaging.

I trust that this information satisfactorily responds to your request. If you need additional information or assistance, please contact Mr. Michael Gidding of my staff at 634-7770.

Sincerely,



Andrew S. Krulwich
General Counsel

U.S. Department of Justice

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90-5-1-0

October 3, 1980

Andrew Krulwich, Esquire
General Counsel
Consumer Product Safety Commission
Room 509
1111 18th Street, N.W.
Washington, D.C. 20207

Re: Request for Advisory Opinion on EPA's Special Packaging Regulations.

Dear Mr. Krulwich:

On May 7, 1980, the Environmental Protection Agency was sued by GPS Industries, a manufacturer of swimming pool pesticides. The suit, currently pending in the district court for the District of Columbia (Civil Action No. 80-1163), is a challenge to EPA's regulations for special (child resistant) packaging, found at 40 C.F.R. §162.16.

Shortly after the suit was filed, Ms. Linda Fentiman, an attorney with EPA's Office of General Counsel, contacted Mr. Michael Gidding and requested an advisory opinion from the Office of General Counsel of the CPSC concerning the following two questions raised by this suit:

1) Whether EPA's special packaging regulations are consistent with standards established by the Consumer Product Safety Commission and its predecessor, the Food and Drug Administration, under the Poison Prevention Packaging Act of 1970, 15 U.S.C. §1471 et. seq.

2) CPSC's interpretation of the meaning of the terms "technically feasible, practicable, and appropriate".

It is my understanding that a draft opinion has been prepared, and that a final opinion will be forthcoming shortly. This letter will formalize Ms. Fentiman's earlier request.

It is our intention to ask the court to take judicial notice of the advisory opinion during the pending proceedings.

I appreciate your assistance on this matter. Please contact me if there is anything I can do to assist you.

Sincerely,

Assistant Attorney General
Land and Natural Resources Division

By: Peter G. Beeson

Peter G. Beeson
Attorney, Environmental Enforcement Section

cc: Michael Gidding, Esquire