

there is no reason why these guidelines should not become effective as quickly as possible.

VII. Environmental Protection Agency

The Environmental Protection Agency ("EPA") enforces the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), as amended (7 U.S.C. 136-136y). Under that Act, EPA has the authority to protect people and the environment from the adverse effects of pesticides by ensuring that pesticide products are applied, stored, and disposed of in a manner consistent with the product registration.

The Administrator of EPA is authorized to establish standards with respect to the package, container, or wrapper in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by FIFRA. FIFRA specifies that the standards established by EPA must be consistent with those established under the authority of the PPPA. Thus, packages that comply with the PPPA regulations would also comply with the standards established by EPA for products regulated under FIFRA. However, EPA would retain the authority to exempt products, either completely or under stated conditions, from the requirement that products regulated under FIFRA have CRP.

Since the Commission is amending its regulations under the PPPA, EPA can be expected to make any necessary amendments to its regulations for packaging so that EPA's regulations will be consistent with those established by the Commission. However, the Commission is not in a position to fully assess how the changes may affect all the products subject to regulation by EPA under FIFRA. For example, some of the containers subject to FIFRA are much larger, and have much larger and more massive closures, than do the household products regulated by CPSC under the PPPA. Such products, that comply with the present PPPA requirements, may not be able to comply with the senior-adult test panel or reduced testing times being proposed for products subject to the PPPA. However, if necessary, EPA has the option of allowing certain containers to comply with a standard incorporating a 5-minute test of the 18-45 age group.

VIII. Regulatory Flexibility Analysis [236]

A. General

The Regulatory Flexibility Act (Pub. L. No. 96-345) requires agencies to prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the rule on small businesses and other small entities, when a notice of proposed rulemaking is published in the **Federal Register**. In its proposal to revise the protocol for testing CRP under the PPPA, the Commission made an initial determination that the effect of the revisions depended upon the amount of package testing needed and the potential cost of research and development and equipment modification, if necessary, to enable closures/packages to meet the revised test protocol. The potential cost of meeting marketing requirements of other government agencies was also unknown.

CPSC received comments on the proposal that provided information on anticipated impacts on companies. Some comments were specific to an individual company; some comments were more generalized and came from trade associations representing small and large businesses. The types of businesses impacted by the proposed revisions include: closure/package manufacturers; household product manufacturers/packagers, pharmaceutical packagers, and pharmacies.

Estimates of the number of businesses in the various market segments are based on data from government sources, trade associations, and trade publications. These sources did not provide specific information on the size of the firms. Small entities that are unaffiliated with trade organizations and that did not comment on the proposal are included in the estimates only to the extent that they reported (anonymously) to government sources.

B. Closure Manufacturers

The Bureau of the Census reported 1991 CR shipment data from 40 or fewer manufacturers (none by name). However, CPSC staff identified about 70 manufacturers of CR closures, many of which were likely included in the Census data. According to industry spokespersons, the CR closure segment of the market is highly concentrated, with the 4 largest manufacturers of plastic closures accounting for an estimated 80% of the CR closure market. [236] Few, if any, of the more than 60 other manufacturers (an unknown number of which may be small) produce

CRP as a primary product line, since the CR market is itself only a small fraction of the closure market.

At a minimum, closure manufacturers will incur the costs of testing existing packages for SAUE. Failing packaging cannot be filled after the expiration of the 18-month exemption from compliance (unless an additional temporary stay of enforcement is granted), but such packaging may be modified or redesigned if economically feasible. The costs of changes are expected to fall on the customer and, in most cases, to pass through to the consumer. It is unlikely that a substantial number of small firms will experience severe or permanent adverse impacts as a consequence of the final rule.

CPSC received only one comment from a self-identified small business that expected "onerous and undue hardship." CR closures account for 20% of this company's business. One aspect of the burden concerns timing, which the Commission has addressed by granting an 18-month exemption from compliance after the effective date. In addition, the company can apply for an additional temporary stay of enforcement if good-faith efforts do not enable compliance by the expiration of the 18-month exemption.

C. Household Product Manufacturers and Packagers

Two trade associations, representing over 900 firms, commented on the proposal. One association said about 65% of its members (almost 300) were small businesses; the other association (representing about 500 members) did not respond to a staff request for this information. Comments from the associations and from several large household product manufacturers centered around the cost of testing, the availability of packaging, and the timing of the implementation of the rule. CPSC did not receive comments from individual self-identified small household product manufacturers or packagers. The manufacturers and packagers of household products that must be packaged in metal containers or aerosol form will benefit from the Commission's decision not to include these products within the scope of the products subject to the senior-friendly requirements of the revised rule.

Small household product manufacturers will incur the costs of testing proprietary packages, if they use such packaging. Economic considerations will guide decisions by small companies on whether to pursue SAUE package development (if proprietary packages fail the revised