UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

CPSA 6 (b)(1) Cleared
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Memorandum

Date: OCT – 7 1999

TO : Mary Sheila Gall, Commissioner

FROM : Ronald L. Medford, Assistant Executive Director for Hazard Identification and Reduction
Suzanne Barone, Ph.D. Project Manager for Poison Prevention, Directorate for Health Sciences

SUBJECT : Responses to Follow-up Questions From Commissioner Gall Regarding Hydrocarbons

1. *Did the staff follow-up with the Plastic Bottle Corporation regarding their comments on costs involved in switching to CR containers?*

Yes, the staff called Mr. Feen, the President of the Plastic Bottle Corporation. Mr. Feen stated that he had no technical basis for saying that the costs of child-resistant packaging would be greater than the benefits. He made his statements based on his personal philosophy about unnecessary regulations and the lack of parental responsibility. Mr. Feen told the staff that it was his recollection that the rule would require child-resistant packaging of motor oil. We informed Mr. Feen that the proposed rule recommended by the staff does not apply to most motor oils because the viscosities of these products are much higher than 100 SUS.

Mr. Feen did not know how or if the rule would affect his business. His company currently has 235 sets of molds for different bottle styles. Mr. Feen indicated that new molds cost about $2,000 to $8,000 per set. The Plastic Bottle Corporation does supply bottles for child-resistant closures. The Plastic Bottle Corporation website (www.plasticbottle.com) describes the types of dimensions that are necessary to accommodate child-resistant closure types. An article on the website discusses the necessity of obtaining closure samples and information prior to a product run, especially for child-resistant packaging.

2. *Did staff contact the Perrego Company for further information on why they said they would need 18 months to comply with the proposed regulation?*

The staff contacted the Perrego Company several times in 1998 to ask about the cost figures they cited in their comment. Melissa McDonald, the Regulatory Affairs Administrator who signed the comment, no longer works at Perrego. The staff was referred to Valerie Gallagher. Ms. Gallagher did not provide the requested information after promising to do so. The staff stopped calling in its initial effort after the fourth

request. In more recent attempts, we were referred to Ms. Luyendyk. Ms. Luyendyk also failed to return our calls. After several attempts, the staff stopped calling.

In its comments, Perrego included a lotion product, bath oils, tanning oils and baby oils in their estimates of products that would need child-resistant packaging. However, the lotion product would not be covered by the proposed rule recommended by the staff because it is an emulsion. It is not known whether any of the bath or tanning oils would be covered; it depends on their viscosities. According to their submission, Perrego requested 18 months because they "felt" that closure manufacturers would not be able to respond to the demand. They supplied no documentation from closure manufacturers directly. However, closure manufacters that were contacted by the CPSC staff indicated that packaging was available or could be developed within a year for hydrocarbon-containing products.

3. *CSMA, in their written comment, referred to the AAPCC data listing 20 fatalities to children under the age of 6 from 1990 to 1994 caused by hydrocarbons. Six cases were from products already regulated under PPPA; two cases were associated with chlorofluorocarbons and thus not relevant; ten cases pertained to gasoline and kerosene. Did the staff investigate the circumstances of the remaining two deaths that CSMA encouraged staff to do? If not, please do so and share that information with me.*

The staff obtains abstracts from the AAPCC detailing the deaths of children under 5 years of age. The deaths cited by the CSMA occurred in 1991 and 1993. According to the AAPCC, the 1991 death was a 3-year old boy who ingested a fabric protector that contained mineral spirits. The child died after 19 days in the hospital. The 1993 death was a 15-month-old girl who ingested an unidentified hydrocarbon stored in a container of glass cleaner. The bottle contained a mixture of ingredients including hydrocarbons. She had lung symptoms consistent with hydrocarbon aspiration and died about 24 hours later. The AAPCC data does not provide sufficient information to enable us to contact the families. Therefore, it was not possible for the staff to follow up on these cases.

Injury Data:

1. *Please explain what volume/amount of hydrocarbon a young child would need to ingest in order to be at risk of serious injury from aspirating this substance.*

It is difficult to define the absolute minimum amount of hydrocarbon that a child must ingest in order to aspirate enough hydrocarbons into the lung to result in pulmonary damage. Multiple factors, including product viscosity, other chemical additives, volume swallowed, and vomiting, play a role in determining whether a product will be aspirated following ingestion. According to medical literature, in most ingestion cases it is very difficult to quantify the amount of hydrocarbon ingested.

In the preamble to the rule requiring child-resistant packaging for furniture polish, the FDA stated that aspiration of 4 mls (approximately one swallow) could result in serious injury or death (36 FR 1971). The restricted flow provision of the PPPA regulations limits the accessible volume of furniture polish to 2 mls per activation. However, the Commission has taken a more conservative approach with the policy recommending that manufacturers, importers, distributors, and retailers totally eliminate the use of hazardous substances in children's products. This policy was codified (16 CFR §1500.231) in 1998 and specifically lists many of the hydrocarbon chemicals as examples of chemicals which the Commission recommends that manufacturers eliminate in children's products.

2. *Staff does have some specific data on baby oil ingestions and subsequent aspiration toxicity. What steps would staff need to take to collect injury data specific to the scope of products this recommended regulation would cover?*
   Staff says that low viscosity hydrocarbons pose a serious aspiration hazard to young children. In order to obtain a better understanding of the likelihood of serious risk of injury to young children by aspiration, staff needs to supply incident data that <u>includes</u> the product lines under the scope of this proposal, rather than a broad spectrum of all products containing hydrocarbons. The injury data should note those products already in CR packaging (both mandatory and voluntary).

Note: We have combined the second injury data question with the exposure question because we believe that the same answer addresses both issues.

The purpose of this rulemaking is to require child-resistant packaging of products that contain chemicals that are known to cause serious injury or illness to children. The staff defined the scope of the products as those that contain more than 10% hydrocarbons and that have a viscosity of less than 100 SUS at 100°F. We then identified several products that contained those chemicals. We looked at ingestion data to show that children access the product categories that contain hydrocarbons. We did not include product categories that already require child-resistant packaging. We have not identified every product that may be affected by this rule. The staff recommends this rule to protect children from serious injury from products that contain chemicals already established as having the potential for serious injury if ingested. Some of these chemicals already require child-resistant packaging when they are in certain product categories, such as furniture polish. The non-petroleum-derived hydrocarbons, such as limonene, have the same chemical characteristics and potential for injury as the petroleum distillates.

It is not possible for us to identify each product and to collect ingestion data on individual products. The difficulty in trying to do this is that we do not know which products contain hydrocarbons at the viscosity level associated with the aspiration hazard. The staff is making its recommendation to the Commission based on the principle that hydrocarbons are clearly established as a hazardous substance. These chemicals are an aspiration hazard and children are gaining access to the types of products that contain these substances.

Cost Data:

1. *There is no economic data providing the costs to industry. Staff suggests that changing to CR screw top caps currently on the market can accommodate the majority of product lines. Has staff followed up with any manufacturers (especially those who sent in comments) to ascertain exactly what would be involved for them to change to CR containers. (production time/costs)?*

The concerns of most of the individual companies that commented on the costs have been addressed by the scope of the rule. In many cases, these products will not be included because of their viscosities or the mechanism of dispensing that the products use. For example, one company makes aerosols; they are not included in the staff's proposal. Several companies make motor oil; these products have high viscosities and are not included. Another company made a battery cleaner similar to a marker; they are not included in the rule because the hydrocarbon is not accessible. One commenter's company made adhesives that were over 100 SUS in viscosity. Most of the negative comments came from trade associations that did not identify the individual member companies. The staff met with several companies, including an automotive product company and several cosmetic companies. Each company provided very little information to support their general claims about costs and timing.

2. *Has staff investigated the availability of supply with closure manufacturers to accommodate this broad scope of product lines?*

The staff discussed packaging availability with several different closure manufacturers in the process of determining technical feasibility, practicability, and appropriateness. Manufacturers indicated that one year was adequate to supply closures for the hydrocarbon-containing products. In addition, Rexam Closures, a large closure manufacturer, submitted a comment on the ANPR indicating that they were developing packaging.

Canadian Standard:

The Canadian Government, which is currently undertaking a similar rulemaking proceeding, submitted extensive comments in response to the ANPR in which it sought to reach "harmony" with our prospective rules. The CPSC and the Canadian Product Safety Branch have in effect an MOU that requires that "each Party shall make compatible" safety standards "to the greatest extent possible". There are similar provisions contained in the NAFTA agreement.

1. *In doing so, please discuss, in detail, the similarities and differences between our two proposals, at this stage of development. Include the types of products and chemical formulations that would be included and excluded, the differences in the percentages of chemicals and levels of viscosity, as well as any other significant areas of agreement and disagreement.*

2. *Discuss the reasoning behind any differences and each Party's justification for the superiority of its own preferred approach.*
3. *Please discuss in detail the safety implications, if any, were this Agency to defer to the Canadian approach in each area of disagreement.*
4. *Please discuss the extent to which you have been in direct contact with the appropriate Canadian officials or staff in order bring to the table these cited differences.*
5. *Please discuss specific areas where it may be more or less likely to arrive at reasonable compromises in order to arrive at harmonization. Include any safety implications of either Party's deviating from its preferred approach.*
6. *Please discuss the best approach for you to undertake, at this point in time, for the two Parties to work actively to arrive at greater harmonization.*

The proposed Canadian regulations combine packaging and labeling provisions into one regulation. The Canadian proposal states that all products regulated under the Hazardous Products Act, defined as toxic by Canada must be in child-resistant packaging. They have criteria that define toxic. In some cases these are similar to the FHSA criteria for labeling. The Canadians do not need to make specific findings to require child-resistant packaging for the household chemical products that they regulate. The fact that a product is toxic is sufficient to trigger child-resistant packaging requirements without the need for ingestion or injury data. This approach is very similar to the EPA criteria that determine whether a pesticide must be in child-resistant packaging, based solely on the toxicity of the chemical composition.

The Canadian rulemaking activity will require child-resistant packaging of many products that currently do not require child-resistant packaging in the United States including, many acids. The area of disagreement you are specifically inquiring about is the Canadian definition of toxicity due to aspiration. The Canadian proposal includes the following:

"A consumer chemical product must be classified in the sub-category "toxic" if it has a viscosity of 14 cSt or less at 40EC (approximately 74 SUS at 104°F) and contains at least 10% of a substance that poses an aspiration hazard, including, in particular, any of the following substances:

(a) an n-primary alcohol with a carbon chain of at least C3 but not more than C13;
(b) an isobutyl alcohol;
(c) a terpene alcohol;
(d) a ketone with a carbon chain of at least C3 but not more than C13;
(e) a hydrocarbon with a carbon chain of at least C3 but not more than C13; or
(f) a substance that has been determined to be an aspiration hazard based on its viscosity, surface tension, and water solubility through the application of generally accepted standards of good scientific practices."

This proposal by Canada includes many more chemical classes than the CPSC staff is recommending. The current CPSC staff recommendation requires packaging of

products that contain more than 10% of any hydrocarbon combination and that have a viscosity of less than 100 SUS at 100°F. This differs in scope from the Canadian proposal part (e) above. The Canadian proposal has a different viscosity that translates to about 74 SUS at 104°F. However, most importantly, we were informed by the Chemical Specialty Manufacturers Association that they were not aware of household chemical products that fell between the two viscosity levels. Therefore, in practice there may not be a significant difference in the number of consumer products that would require child-resistant packaging under the Canadian vs. CPSC recommendations. These Canadian regulations under the Hazardous Products Act do not extend to the labeling and packaging of cosmetics and drug products which are regulated under the Canadian Food and Drugs Act. Therefore, the mineral-oil-type products that are considered cosmetics and are included in the CPSC staff's proposal are not included in the Canadian proposal.

The CPSC staff recommendation maintains the viscosity at the level of less than 100 SUS because of the injuries and death associated with lightweight mineral oils, such as baby oil with a viscosity in the 60-75 SUS range. The products that include these chemicals are cosmetics. The Canadian regulations regarding child-resistant packaging for cosmetics lag behind those of the CPSC. The Canadian standards have required child-resistant packaging of cosmetics containing bromates and acetonitrile since 1995. These products required child-resistant packaging in the United States since 1991. The Canadians have just drafted a standard to require child-resistant packaging of cosmetics containing methacrylic acid and ethanol-containing mouthwash. Mouthwash has required child-resistant packaging in this country since 1995. The Commission requirement for child-resistant packaging of methacrylic acid will be effective June 19, 2000. The Canadian government has not proposed cosmetic regulations that would parallel the regulations proposed by the chemical product side of the Canadian government.

In conclusion, the staff recognizes that the regulatory approach taken by the Product Safety Bureau in Canada is different than in the United States. However, the practical effect with respect to hydrocarbons regulated by the Hazardous Products Act (which does not include cosmetics), is that most consumer products that fall within the scope of the CPSC staff recommended rule will be included in the Canadian proceeding. The most significant difference lies with some cosmetic products that contain mineral oil. However, the Canadian cosmetic regulations have followed CPSC's work on child-resistant packaging rather closely. As indicated earlier, the Canadian regulatory process for child-resistant packaging is self-effectuating. Products that meet the definition of toxic as defined by the Product Safety Bureau in Canada are required automatically to be in child-resistant packaging. This basic difference between our regulatory approaches will mean that there will not be uniformity between our two countries. The Canadian approach will require more products be placed in child-resistant packaging than in the United States.