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August 16, 2010

Dear Mr. Williams:

Johnson & Johnson Consumer Companies, a participant in the pilot phase of the rule making process, appreciates the opportunity to comment on the preliminary rules for the Children's Safe Products Act. Our comments apply to cosmetic products, which are regulated by the US Food and Drug Administration.

During the pilot phase of the project, the Department of Ecology (DoE) sought

*"Any data/suggestions which might help us determine the reporting trigger values. This could include risk assessments, 'safe harbor' values from other authoritative bodies, assumptions used to determine likely migration of chemicals, etc."*

The present rule deviates from this publically stated road map and proposes a "one-size fits all" framework of reporting ranges that are far too granular at the low end. The concern is that this reporting framework for trace levels will not result in meaningful information that can be used by the DoE to assess exposures. Potential exposures are a function of the product category and exposure pathways. Moreover, the 10 ppm threshold is independent of individual chemical risks and can be taken out of context.

In order to assure compliance under a 10ppm level, the manufacturer has two choices:

1. Develop a test method for every combination of product and chemical that is likely to be a trace or
2. Overestimate the level present and report a range that is likely in excess of the actual material present.

Actual testing for traces is cost prohibitive. To do this, companies would be obligated to develop and validate a method for every trace chemical on the list and product combination.

- The cost to develop and validate a method for a trace metal in one product is estimated to be: \$20 to \$30K for each test method and take 6 to 8 weeks.
- Analysis of individual samples for a trace metal could cost \$500/sample and 1 to 2 weeks time.
- J&J is currently evaluating the test methods proposed by the DoE. Until that work is complete, it is unclear whether the reporting ranges are appropriate. For example, the method to accurately measure formaldehyde released in solution by formaldehyde donor preservatives is cost prohibitive and not widely available. Therefore, it is likely that the method to assess formaldehyde proposed by the Department of Ecology will overstate the amount present, and result in ongoing disputes over the actual amount of exposure.
- To repeat, because of the granularity of the reporting ranges at the low end, this rule will cause the manufacturer to overstate the actual traces present to ensure compliance or resort to costly

test method development. This will not serve the consumer well and will be taken out of context.

Under the current toxicological methods for safety assessments of ingredients and products, our scientific experts often estimate “worst-case” exposures and then determine a margin of safety. We ensure that we are well under thresholds determined by authoritative bodies, such as those set by California’s Proposition 65. This framework establishes that the exposures are safe; it does not provide a quantitative amount to determine reportability at 10ppm.

With this in mind, we reiterate the need to establish a *de minimis* threshold for reporting. Therefore, we request that a *de minimis* threshold of no less than 100ppm be set for intentionally added and trace chemicals used in cosmetic products. That provides us with a feasible way of managing traces in products. Critical traces are managed through specifications and certificates of analysis.

In a review of the final list of “Chemicals of High Concern for Children” (CHCC), we note that cadmium was a recent addition to the list and that cadmium has not been subject to public discussion. The CPSA prohibits the sale of products with cadmium at more than 40 ppm. Therefore, if a manufacturer cannot assure that the level is less than 10 ppm, it is likely that a manufacturer will report 10-100ppm, which leads to questions or possible litigation as to whether the product is in compliance with the underlying statute. We recommend a reporting requirement of greater than 40ppm. Else, we can apply the same reporting threshold proposed during the pilot phase for heavy metals, which is total heavy metals greater than 20ppm and lead greater than 10ppm.

Current regulations require that parabens be listed on the product label; therefore, reporting is redundant and does not provide any additional information on their use. The FDA has this information as part of the Voluntary Cosmetics Reporting Program, and summaries on the use of parabens can be obtained from the US FDA. Propylparaben, butylparaben, methylparaben, and ethylparaben should be removed from the CHCC list. Alternatively, we propose exempting any chemical on the CHCC list from the reporting requirement if it is listed on the product packaging.

Some trace level guidelines are available through authoritative bodies. The materials listed in the following table are traces and not intentionally added. It is possible that they could be detected at very low levels in a few products. While it may be possible to minimize their presence; complete elimination is not feasible. When a source is listed parenthetically, this indicates that the trace level is found acceptable up to the restriction level. When USP is the source, the trace level is found acceptable up to the threshold listed in orally ingested pharmaceutical products. For all of the other chemicals on the CHCC list, we propose implementation of a *de minimis* level of 100, which is consistent with proposed regulations elsewhere in the United States.

**Trace / Incidental Ingredients with Suggested de minimis Level**

<b>CAS No.</b>	<b>Ingredient (INCI name if different)</b>	<b>Restriction (Source)</b>
50-00-0	Formaldehyde (this refers to formaldehyde in solution, not the gas)	<500 ppm (EU warning requirement)  Permitted up to 0.2% (EU Annex VI). All finished products containing formaldehyde or substances in ANNEX VI which release formaldehyde must be labeled with the warning "contains formaldehyde" where the concentration of formaldehyde in the finished product exceeds 0.05%.  Quaternium-15 max use limit 0.2%  DMDM Hydantoin max use limit 0.6%
78-93-3	Methyl ethyl ketone (MEK)	<5000 ppm (USP)
107-21-1	Ethylene Glycol (Glycol)	<620 ppm (USP)
108-88-3	Toluene	<890 ppm (USP)
108-95-2	Phenol	<100 ppm
872-50-4	N-Methylpyrrolidone (Methyl Pyrrolidone)	<530 ppm (USP)
7439-97-6	Mercury & Mercury compounds including Methyl Mercury (22967-92-6) (Thimerosal)	Ingredient prohibited (EU Annex II)  Total heavy metals as unavoidable traces <20 ppm (German MOH)
7440-36-0	Antimony & Antimony compounds (Antimony Potassium Tartrate)	Ingredient prohibited (EU Annex II)  Total heavy metals as unavoidable trace <20 ppm (German MOH)
7440-48-4	Cobalt & Cobalt compounds (Cobalt Aluminum Oxide)	Ingredient prohibited (EU Annex II)  Total heavy metal as unavoidable trace <20 ppm (German MOH)

The Department of Ecology requested thoughts on alternative assessments. We believe that continuous product improvement and safety are integral components of such assessments, and Johnson & Johnson Consumer Companies, Inc. are committed to continuous improvement of our products. Furthermore, there is absolutely nothing more important to us than the safety and well-being of babies and all of our consumers. To ensure that we are offering safe products, we do the following:

- We specifically formulate our baby products to meet their unique cleansing needs.

- The best and most complete science substantiates the safety of our products in use, and we are continuously reviewing and assessing the science.
- Our products are comprehensively evaluated for safety, prior to introducing a product into the marketplace.
- Healthcare professionals review our safety data, are familiar with all of the steps we take, and have confidence in our products.
- We have a well developed system to track consumer feedback and evaluate safety data, and we are continually reviewing new scientific studies, regulations and stakeholder input. If credible, new evidence raises concerns about an ingredient—even if it meets government regulatory requirements—we will reduce or eliminate it, as needed, to ensure the highest levels of safety. In addition, we may also reformulate products for a number of other reasons including: new scientific information, better performance, changing consumer preferences and stakeholder input, and to reduce environmental impact.
- We are researching the next generation of baby product ingredients. Of course, if we replace an ingredient, it must also meet our rigorous standards and be proven and tested to be safe before we use it. We are committed to continuously evolve our products to support the changing nature of personal care. In doing so, it is our goal – and commitment – to set high standards for the industry.

The safety of our products is supported by clinical testing, independent review by leading healthcare experts, international regulatory agencies, and many years of real-world use by babies and other consumers. Federal regulatory agencies in the U.S. and Europe have reviewed the science and concluded that the trace levels of certain compounds are present in such extremely small amounts they are completely safe.

As is required under the Federal Food, Drug, and Cosmetic Act, the substantiation of safety is the responsibility of the manufacturer. We have hundreds of scientists and experts in Research and Development; it is redundant and a waste of the state's limited resources to develop a staff of experts to develop a credible program to evaluate the ingredients used in cosmetic products and make recommendations for alternatives. Furthermore, the one year extension of the reporting requirement to encourage alternatives assessments could be used to delay reporting required under the rule.

Thank you for your consideration of our comments.

Sincerely,

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