WOMEN'S VOICES FOR THE EARTH

OUR HEALTH. OUR FUTURE. TOXIC FREE.

November 21, 2018

To the CIR,

I am writing to provide comments on the revised Aerosol CIR Precedents document. I greatly appreciate the extensive discussions and considerations of my previous comments on this issue. However, I remain concerned that

1) the boilerplate language continues to make broad assumptions and conclusions of safety about the inhalation of cosmetic products that are not supported by the data.
2) the narrow focus on just hairsprays and aerosol deodorants is severely limiting, given the numerous other cosmetic products that come in spray form, which may have considerably different ingredients, exposure levels and use frequencies.
3) the boilerplate language regarding exposure to cosmetic powders has not been updated, and still reflects assumptions of safety based solely on talc data from 1979, which is not only outdated but is likely not reflective of all cosmetic exposures.
4) the citations for several of the newly included calculation examples do not correspond to the relevant papers and should be corrected and,
5) while there is more nuanced discussion in the background section of the Precedent document, the actual boilerplate language includes the following sentence:
"*Particle/droplet size data under consumer use conditions are rarely needed when assessing the inhalation safety of an ingredient in a spray cosmetic product*."
I believe this assertion, which could be included in isolation in a safety assessment, reflects poorly on the scientific understanding of the CIR.

1) The boilerplate language continues to make broad assumptions and conclusions of safety about the inhalation of cosmetic products that are not supported by the data.

At the very beginning of the Cosmetics Use Section of the boilerplate language it states:

"*In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 µm [IF PRODUCT(S) MAY INCLUDE BOTH PROPELLANT AND PUMP SPRAYS, ADD: , with propellant sprays yielding a greater fraction of droplets/particles below 10 µm compared with pump sprays]. (Rothe et al 2011, Bremmer et al 2006, Rothe 2011, Johnsen 2004).*[1,12,17,46] *Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (ie, they would not enter the lungs) to any appreciable amount. Rothe et al 2011, Bremmer et al 2006).*[1,12] *[IF PRODUCT(S) INCLUDE DEODORANT SPRAY(S), ADD:*

There is some evidence indicating that deodorant spray products can release substantially larger fractions of particulates having aerodynamic equivalent diameters in the range considered to be respirable (Bremmer et al 2006).[12]

The data currently available to the CIR includes particle size distributions solely for hairsprays and deodorant sprays. (This includes the ConExpo Model data (Bremmer 2006) as well as the new data submitted to the CIR by industry for this document.) Hairsprays have been generally found to have 95% of particles >10 *μm,* while deodorant sprays have been found to have only 50% of particles >10 *μm.* The boilerplate language, however, inaccurately generalizes the hairspray data and applies it to all "cosmetic sprays". (There is simply no data on any other cosmetic sprays other than deodorant sprays to corroborate this assumption.)
Then later, as if in contrast, the document states there is "*some evidence indicating that deodorant spray products can release substantially larger fractions…"* The particle size data on deodorant sprays is actually coming from the very same sources as the hairspray data, and should be given equal weight and credibility and should be clearly stated as 50%.

Given that, it is illogical to conclude "*Therefore, **most droplets/particles** incidentally inhaled from **cosmetic sprays** would be deposited in the nasopharyngeal and bronchial regions and **would not be respirable** (ie, they would not enter the lungs) to any appreciable amount)."*
Again, this statement is conflating conclusions from data on hairsprays with all cosmetic sprays. The term "cosmetic sprays" clearly includes deodorant sprays, and for deodorant sprays it is inaccurate to state that "most" particles would not be respirable, when the data tells us that at least half of particles would be respirable.

2) **"Cosmetic sprays" incorporate numerous different products not considered by this analysis**.
In addition to hair sprays and deodorant sprays, cosmetic of many kinds can come in spray form and potentially be inhaled. These cosmetic sprays include different ingredients and have different exposure patterns than either hairsprays or deodorant sprays. Specifically, cosmetic products include:

Airbrush makeup (this is done at home as well as professionally)
If you are unfamiliar with this cosmetic product, I highly recommend the following video tutorial of how to apply airbrush makeup at home:
https://www.youtube.com/watch?v=yBPry8aJ3oY
You will see in this video that the airbrush makeup is sprayed directly to the face, and full application of airbrush foundation takes about four minutes of near-continuous spraying. (Learning to use this tool – would certainly involve longer application times, and additional layers of airbrush rouge, eye shadow etc can also be sprayed in addition, further increasing the exposure time.) The exposure time to this cosmetic spray is clearly significantly longer than exposures to hair spray or deodorant spray. Particle sizes for airbrush makeup are not currently available, but particles are likely to be quite small as larger particles would clog the airbrush.

Sunless tanning
Similarly, sunless tanning products are commonly applied in spray form to get an even overall look. In addition to spraying directly at the face, spray tans can also be applied over the entire body. Full body application of spray tans can take up to 15-20 minutes of continuous spraying. Particle sizes for sunless tanning cosmetic sprays are currently not available.

Spray-on hair color
These products are very popular currently, especially among children and teens, with products affording color that lasts just one day, to more lasting colors. To get a sense of potential amount of usage, a single can of "Colorista 1-day-spray" contains 57 grams of product. According to the manufacturer's website
"*If you're looking for allover color, you may need to use more than one can*."
https://www.lorealparisusa.com/beauty-magazine/hair-color/hair-color-trends/how-to-use-colorista-1-day-sprays.aspx

Other cosmetic sprays not addressed in the boilerplate language include:

Spray lotion (including both sunblock aerosol sprays and moisturizing lotion sprays)
Spray on nail polish (and airbrush nail polish)
Lacewig adhesive spray (and hair glue remover sprays)

The Aerosols boilerplate language refers generally to "cosmetic sprays" and comes to assumed conclusions of safety largely based on the following assumption:

"In practice, exposure to an ingredient during the application of cosmetic sprays will be very low, due to low use quantities and very short exposure times."

There is no available data on these types of cosmetic sprays that could corroborate this assumption is also true for these products and their potential exposures.

3) The boilerplate language regarding exposure to cosmetic powders has not been updated, and still reflects assumptions of safety based solely on talc data from 1979.

With respect to inhalation hazards of cosmetic powders, the boilerplate language states:

"Conservative estimates of inhalation exposures to respirable particles during the use of loose powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace. (Aylott et al 1979, Russell et al 1979, CIR SSC 2015).[38-40]]

In my previous comments I raised a concern that the assurances of safety of inhalation of cosmetic powders should be based on more recent data than what was available in 1979, using outdated technology. However, despite what appears from the transcripts to be agreement among the CIR members that there should be newer data, no new data on particle size distribution of powders has been included in the latest revision.

The claim that inhalation exposures to respirable particles are 400-1000 fold less than regulatory guidelines is derived from calculations made in 2015 by the CIR SSC based on reported airborne concentrations of respirable particles from the use of talc powder which come from the 1979 data (Aylott et al 1979, Russell et al 1979). This is inappropriate, when the issue has been raised and discussed that better and more accurate technology is now available to measure airborne concentrations of respirable particles from cosmetic powders.

For example, the Malvern company (which makes one of the most popular particle sizers - the Mastersizer 3000) published a paper on particle size distribution of cosmetic "mineral makeup" powders. The paper entitled "Morphologi G3: Understanding Mineral-based Make-up using Size, Shape and Intensity Measurements" is available at: https://kdsi.ru/upload/iblock/967/967d6aaf3337ef0e88bac0fd599a881b.pdf They found that for three commercially available mineral make-up products, a veil, a foundation and a bronze, 48 – 66% of the particles were smaller than 10 microns in diameter. They explain that particle size is specifically engineered to support the function of the powder. "*Particle size in the powder affects the final make up appearance where extremes lead to a poor finish. When the particles are too large a powdery look is observed and when the particles are too small there is an insufficient masking effect*." It appears that manufacturers, if asked, should be able to provide particle size information about their cosmetic powders currently on the market, as many products will be designed with particle size specifications in mind.

Also, reflecting the advances in technology, the paper states:
"*Particle imaging is a discipline that was once labor-intensive and highly subjective because it was performed manually. The development of automated particle imaging instruments equipped with integrated computer-controlled dispersion, advanced image processing and statistical analysis tools, such as the Morphologi G3S, have taken this informative technique to a new level."*

The CIR should simply have the best and most recent data at its disposal to ensure the safety of inhalation of cosmetic powders. The discussion and analysis of cosmetic powders should also go beyond talc which is currently the only example being considered by the CIR.

4) Examples of incorrect citations in the Aerosols Precedent document

The document includes the following calculation:

"For example, conservative estimates indicate that inhalation exposures for once-a-day application of a pump hair spray, propellant hair spray or propellant deodorant spray containing 2% of an ingredient would be no more than 1.5, 4.7, and 6.8 µg/kg/day, respectively.[35,36] These estimates were based on the following conservative assumptions:

• All of the spray enters the breathing zone (i.e., 100% is available for inhalation)
• Two-box exposure model: the droplets/particles distribute in 1000 L in the first 2 minutes, and distribute 10,000 L in the next 18 minutes
• 25% of the inhaled droplets/particles are exhaled
• Breathing rate: 10 L/minute

• Body weight: 60 kg
• Amount of product used: 15.6, 9.89 and 1.43 g/day pump-hair, propellant-hair, and propellant deodorant spray, respectively [37]
• Respirable fraction: 1%, 5%, 50% for pump-hair, propellant-hair and deodorant spray, Respectively"

I was particularly interested in the citation #37, cited as the source for "*Amount of product used: 15.6, 9.89 and 1.43 g/day pump-hair, propellant-hair, and propellant deodorant spray, respectively [37]*

However, citation #37 is the following paper: Loretz L, Api AM, Barraj L, Burdick J, Davis de A, Dressler W, Gilberti E, Jarrett G, Mann S, LauriePan YH, Re T, Renskers K, Scrafford C, and Vater S. Exposure data for personal care products: hairspray, spray perfume, liquid foundation, shampoo, body wash, and solid antiperspirant. Food Chem Toxicol. 2006;44(12):2008-2018. PM:16920244

While this paper appears to be a source for hairspray data this paper does not measure amount of product used for propellant deodorant spray, it only measures use of solid antiperspirant. Thus, a citation is needed for the estimate of 1.43 g/day used of propellant deodorant spray.

Similarly, the document later states:

"Literature reports of use amount for one-a-day application of a loose face powder range from 73.1 to 85 mg.[41,42] Assuming 1% of a loose face powder is respirable yields an estimated exposure no more than 0.9 µg/kg/day for a 60 kg person,[43] based on a conservative estimate use of face powder at 510 mg per application per day.[44]"

However, citation 41 is Ficheux, A. S., Wesolek, N, Chevillotte, G, and Roudot, AC. Consumption of cosmetic products by the French population. First part: frequency data. Food Chem.Toxicol. 2015;78:159-169. PM:25680505. This paper reports on a survey of frequency of use of various cosmetic products (ie. how often cosmetics get used) and does not include any data on amount of use for any cosmetic products.

Citation 42 is Loretz, L. J., Api, AM, Babcock, L, Barraj, LM, Burdick, J, Cater, KC, Jarrett, G, Mann, S, Pan, YH,Re, TA, Renskers, KJ, and Scrafford, CG. Exposure data for cosmetic products: facial cleanser, hair conditioner, and eye shadow. Food Chem.Toxicol. 2008;46(5):1516-1524. PM:18243463. This paper only estimates usage of facial cleanser, hair conditioner and eye shadow – and does not discuss loose face powder.

Citation 44 is Scientific Committee on Consumer Safety (SCCS). The SCCS's notes of guidance for the testing of cosmetic ingredients and their safety evaluation (7th Revision). 2010. http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_004.pdf. This is a long report, but I was unable to find any data here corresponding to an estimated use of face powder either. Correct citations in these sections would be appreciated.

5) **Lastly, I caution the CIR from including the following language in the boilerplate: "*Particle/droplet size data under consumer use conditions are rarely needed when assessing the inhalation safety of an ingredient in a spray cosmetic product*."**

This statement appears either to contradict a major tenet of inhalation toxicology, (i.e. that particle size is indeed a significant factor) or to imply that the CIR is simply uninterested in investigating particle size data when they assess an ingredient for inhalation safety.

Thank you for your consideration of these comments.

Sincerely,

Alexandra Scranton
Director of Science and Research
Women's Voices for the Earth