

CIR

Cosmetic Ingredient Review:
Failing the Public.
Failing Manufacturers.

An Investigative Brief by Women's Voices for the Earth





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TABLE OF CONTENTS

Introduction

Who is the CIR?

Major Failings of CIR Safety Assessments

- Conflict of Interest
- Narrow Operating Scope that Excludes Concerns for Workers and Environment
- Overly Broad Conclusions on Inhalation Hazards
- Inadequate Assessment of Data Gaps

Conclusion and Recommendations

References

INTRODUCTION

Ensuring the safety and health of cosmetic products is vitally important. From personal health impacts to down-the-drain effects on our environment, citizens are increasingly concerned about the products they use. Currently, the responsibility for the safety of these products is in the hands of the cosmetics manufacturers themselves.

While manufacturers are required by law to ensure the safety of their products, clear standards for demonstrating safety are woefully lacking. Therefore, establishing an enforceable mechanism or process by which cosmetic manufacturers can demonstrate and substantiate the safety of the ingredients they use is imperative.

It has been proposed that safety assessments conducted by the Cosmetic Ingredient Review are sufficient to meet this need. In this report, we outline four key reasons why reliance on the Cosmetic Ingredient Review (CIR) to assess the safety is inadequate: inherent conflict of interest, a narrow operating scope which excludes major concerns for workers and the environment, overly broad conclusions on inhalation standards, and inadequate assessment of data gaps. We provide examples of previous failures of the CIR to fully substantiate the safety of cosmetic ingredients. Finally, we conclude that reliance on the CIR assessments to determine safety could lead manufacturers to use cosmetic ingredients which are in fact unsafe and make recommendations for an alternative system.

- Conflict of interest
- Narrow operating scope that excludes concerns for workers and the environment
- Overly broad conclusions on inhalation hazards
- Inadequate assessment of data gaps

Of note: The term *cosmetics* includes personal care products, such as, shampoo, lotion, soap, deodorant, makeup, and feminine wipes, washes, and sprays.

WHO IS THE CIR?

The CIR is a program of the Personal Care Products Council (PCPC), a trade organization which represents over 600 cosmetic product manufacturers. The CIR's stated purpose is:

*"The purpose of the Cosmetic Ingredient Review is to determine those cosmetic ingredients for which there is a reasonable certainty in the judgment of competent scientists that the ingredient is safe under its conditions of use."*¹

The CIR is made up of a Steering Committee, CIR staff members, the CIR Science and Support Committee and the CIR Expert Panel all of whom contribute to the published safety assessment of cosmetic ingredients. Management and staffing of the CIR and its committees is paid for and managed by the Personal Care Products Council (PCPC).

CIR Structure and Roles²

The **CIR Steering Committee** provides general policy and direction for the CIR, appoints the CIR Director and selects the CIR Expert Panel members. The CIR Steering Committee includes three industry members, the CEO of the PCPC, who serves as the chair of the Steering Committee, the chair of PCPC's CIR Science and Support Committee (CIR SSC), and PCPC's executive vice president for science in addition to four public members.

The **CIR staff** compiles, curates and produces a draft report on the science on each chemical (or chemical group) for the CIR expert panel members to review and discuss. Staff members attend the CIR expert panel meetings in order to incorporate their input and decisions into the final safety assessments.

The **CIR Science and Support Committee** is a committee of industry scientists which supports the CIR staff with scientific information and advice during the development of a draft safety assessment.

The **CIR Expert Panel** includes toxicologists, dermatologists and other scientists convened to review the draft safety assessments and deliberate on the safety of cosmetic ingredients. The CIR Expert Panel's reports, agendas and minutes are available on the CIR website for public comment. Information on meetings and actions of the CIR Steering Committee and the CIR Science and Support Committee are not publicly available.

While the decisions of the CIR currently have no regulatory power, the members of the PCPC – that is cosmetics manufacturers – are strongly encouraged to comply with CIR determinations to substantiate the safety of the ingredients they use in their products. The PCPC Consumer Commitment Code specifically states that companies may use the safety findings of the CIR for this substantiation. The Code also states that if a member company uses an ingredient in a product that exceeds any limits set by the CIR, that it must possess additional information which substantiates the safety of that ingredient use.³ The PCPC however, does not have a formal enforcement mechanism to ensure this occurs.

MAJOR FAILINGS OF CIR SAFETY ASSESSMENTS

Conflict of Interest

The most obvious problem with the self-regulatory nature of the CIR is that it is paid for and managed by the PCPC, the trade association that represents the major manufacturers (and thus the largest market share) of the cosmetics industry. These companies have an inherent interest in establishing the safety of the ingredients they use, and a significant financial disinterest in public pronouncements that the ingredients they use are unsafe. The influence of the PCPC member companies on the decisions of the CIR is clearly seen in several ways.

A. CIR's decisions are heavily influenced by PCPC activities in ingredient defense

Example: Talc

As part of their operations, the PCPC occasionally engages in activities to defend against efforts that would limit the use of certain ingredients in cosmetics that the industry deems important. The best and clearest example of this work is the PCPC's history of defending the safety of talc. Talc exposure has been linked in numerous studies to increased risk of cancer, specifically ovarian cancer and mesothelioma.^{4,5,6,7,8} Talc exposure is also associated with breathing problems and respiratory disease such as pneumoconiosis.^{9,10} As early as 1993, the PCPC, then called the Cosmetic, Toiletry and Fragrance Association (CTFA), founded the Talc Interested Party Task Force, whose purpose was to pool financial resources from interested manufacturers to defend the safety of talc and prevent regulation of the talc industry. The Task Force submitted testimony to the National Toxicology Program¹¹ and published talc safety information to consumers. The task force also hired scientific consultants to write reports and publish papers that raised doubts on the hazards of talc.¹² Despite public controversy on the safety of talc beginning in the 1970's the CIR did not choose to formally review the safety of talc until 2012. Not surprisingly, when the CIR finally took up their safety assessment of talc in 2012, the arguments made for safety of talc mirrored the very same arguments made over the years by the CTFA and the PCPC.¹³ It is clear from transcripts of the CIR's discussion on talc, that the conclusion of safety was assumed from the very beginning of their relatively brief deliberations. There was only minor discussion of how best to refute (and in fact whether or not it was even worth mentioning) the newest studies linking talc exposure to ovarian cancer.

Excerpts from the transcript of CIR meeting, December 10, 2012, discussion of the safety of talc:

"DR. BERGFELD: Do you think in your discussion that you have to consider pulmonary fibrosis and take up the ovarian studies in some way just to bring all those together?"

DR. BELSITO: Well, the ovarian studies I think are --

DR. BERGFELD: Then why do we give them so many pages?"

DR. BELSITO: Because is (sic) think they're out in the literature. I mean, in the discussion. I mean, I think that -

DR. BERGFELD: But you can negate them. You can negate them in the discussion. You can address them and negate them...."

DR. SNYDER: I think the discussion could be much more abbreviated...."

DR. BELSITO: The discussion hasn't been developed yet, but I mean, I think the whole issue of ovarian cancer, I'm not even sure that needs to be in the discussion."¹⁴

.....

"DR. SLAGA:... There's not really studies to really say it has a relationship, a causative relationship to ovarian cancer...So, I have very little concerns."

DR. SHANK: I agree. If topical application of talc leads to cancer of the ovary, why does it not lead to cancer of the cervix and cancer of the uterus? I think this ovarian cancer situation is not a real problem."¹⁵

At the same time that the CIR was deliberating on the safety of talc, Johnson & Johnson, a major dues-paying member of the PCPC, was engaged in numerous lawsuits on charges that their talc-containing baby powder and feminine powder products were causes of ovarian cancer and pulmonary disease.¹⁶ An adverse finding from the CIR would have been a significant blow to J&J's case, with multi-million dollar ramifications. The CIR Expert Panel concluded that "talc is safe in the present practices of use and concentration."¹⁷

Example: Cocamide DEA

Between 2012 and 2013 both the U.S. National Toxicology Program (NTP) and the state of California Office of Environmental Health Hazard began considering listing Cocamide DEA as a known carcinogen.^{18,19} The Personal Care Products Council submitted comments to these agencies, that despite an NTP study indicating "clear evidence of carcinogenic activity", Cocamide DEA should not be listed as a carcinogen.^{20,21} The PCPC argued that the carcinogenicity of Cocamide DEA was not inherent to the ingredient itself but rather a result of an impurity of "free DEA" found in Cocamide DEA. During this time, the CIR was also discussing the safety of Cocamide DEA. In their safety assessment published in 2013, the CIR also included mention of the NTP study that showed "clear evidence of carcinogenic activity" of Cocamide DEA. The CIR very similarly reasoned that the carcinogenicity of Cocamide DEA in the study was due to "the presence of free DEA", but chose to allow impurities of free DEA at the levels in "present practices of use and concentration". The CIR's final conclusion was that Cocamide DEA was "safe as used" in cosmetics.²²

B. The CIR frequently prioritizes manufacturers' interests to continue use of preservative chemicals over the known health concerns of these chemicals.

Preservatives are important for many cosmetic products as they prevent the growth of bacteria and fungi in these products thus significantly extending their shelf life. Unfortunately, many preservative chemicals were put on the market and incorporated into products well before recent research was conducted indicating potential harm. The focus of most pre-market research was to ensure these chemicals were effective at killing bacteria, but the potential side-effects of health hazards also caused by these products were not carefully examined. Experimental studies conducted in recent years have led scientists to question whether the risks posed by these chemicals may outweigh their benefits of preservation. As a result, a number of preservatives are being taken off the market through regulation and some by voluntary choice of the manufacturers.²³ Many manufacturers, however, concerned about the costs of reformulating their products and being left with few available alternatives, have chosen instead to defend the use of hazardous preservatives, despite demonstrated toxic effects.

Transcripts from the CIR meetings demonstrate that the CIR has supported manufacturers in these efforts by concluding the safety of preservative chemicals in spite of the evidence of harm to public health. The CIR has repeatedly prioritized concerns about the lack of available substitutes over the associated health hazards. The following are some examples of this from the transcripts of CIR meetings.

In December 2011, the CIR discussed whether or not to reopen the safety assessment of the preservative, methyl dibromo glutaronitrile. The CIR was presented with data of high rates of allergic skin reactions to the ingredient, which posed the potential that the CIR could determine the ingredient was unsafe for cosmetic use. The CIR realized, however, that similar (and potentially even more compelling data) was also available for other preservatives on the market, and making an "unsafe" determination on methyl dibromo glutaronitrile could set a precedent for other ingredients.

*"...but my point is I don't think we need to reopen it [methylidibromo glutaronitrile] because if we ban this then we're banning quaternium-15... We're banning diazolidinyl urea. We're banning a whole bunch of other things..."*²⁴

A similar argument is made in a March 2014 meeting regarding high rates of allergy to methylisothiazolinone (MI), which was being restricted in the European Union. Methylisothiazolinone is a component of a similar preservative MCI/MI which also poses an allergy risk.

*"...because the most important thing is that we not ban MI in all product categories because then we're essentially banning MCI/MI."*²⁵

In April 2016, the CIR tackled whether or not to reopen their review of parabens. It seems the CIR was motivated to reopen their review by the imminent threat that the European Union was likely to restrict the use of parabens due to new hazard data. A pre-emptive safety determination of parabens by the CIR was considered a strategy to keep these ingredients on the market, despite ever increasing data on the hazards of parabens.

"...Europe is relooking at parabens, which is the same reason, I think, we need to look at adding the ingredient ... to our priority list so it may be nice to come back and reiterate the U.S. position on parabens, because I am not sure what the Europeans are going to end up doing with it but there is a strong movement among certain groups in the EU to significantly restrict them..."

"I am just pointing it out, sometimes reacting to the EU, it didn't help us with methylidibromo glutaronitrile so, you know, and I think it is helping us a little bit with potentially keeping MI on the market to some extent..."

*"Once the EU has passed a regulation limiting this, it's really too late."*²⁶

Lastly, from the June 2017 meeting's discussion of the preservative "polyaminopropyl biguanide" which is linked to respiratory concerns and allergic reactions:

"Otherwise I think this [polyaminopropyl biguanide] will end up being the next methylisothiazolinone on the market. I'm very concerned about it and I think we are losing so many preservatives that I don't want to see this one lost."²⁷

Despite frank discussion of these clear risks of allergenicity and other harms from these preservative chemicals, the CIR reaffirmed their conclusions of safety in every case. It appears the PCPC's concern of "losing another preservative" trumped the consideration of safety in their evaluation of these chemicals.

Narrow Operating Scope

A conclusion of safety from the CIR, is often presumed to be just that – a conclusion that the use of an ingredient in a cosmetic product poses no harm. There are manufacturers who may rely on CIR safety determinations in lieu of conducting a full risk assessment. However, the reality is that the CIR has a very specific and limited scope in its charge. The CIR is solely determining if a cosmetic ingredient poses harm to human health from its use in a cosmetic product in a consumer setting. Environmental hazards (such as adverse effects on water quality) and occupational hazards (such as may be experienced in a beauty salon) are frequently ignored by the CIR, determined to be irrelevant to their deliberations. A CIR determination of safety therefore is inadequate as a replacement for a full risk assessment of a chemical, which would assess the many risks other than to human health.

A. Dismissal of Environmental Hazards

Example: Nonoxynols

In 2015, the CIR reopened their review of the safety of nonoxynols, in light of a new European regulation which set significantly stricter levels than previously determined safe by the CIR. After further discussion, they found that the scientific rationale for the restrictions in Europe were due to environmental concerns of nonoxynols including endocrine disruption which was considered irrelevant by the CIR. As a result, the CIR felt satisfied in concluding that nonoxynols are "safe in the present practices of use and concentration in cosmetics".

From the June 2015 CIR Post-meeting Announcement:

"The Panel reopened the 1983 and 1999 final safety assessments to gain additional information on the basis for the European Union's (EU) $\leq 0.1\%$ limitation on the concentrations of nonylphenol ethoxylates (another name for nonoxynols) and nonylphenol in cosmetic and other industrial products, in light of the Panel's previous conclusion that restricted the use of nonoxynols in leave-on products to concentrations $< 5\%$. Restrictions in the European Union on the concentrations of nonylphenol and nonylphenol ethoxylates in industrial products is based on the premise that European

*water bodies are at risk from the persistence of the nonoxynols and their degradation products in the environment, and their potential to cause endocrine disruption in ecological species. **The Panel determined that this is not an issue that is relevant for assessing the consumer safety of nonoxynols as used in cosmetic products.***"²⁸ (emphasis added)

Example: Hydrofluorocarbon 152a

Similarly, in June 2017, the CIR reviewed the safety of Hydrofluorocarbon 152a, in response to regulations of this chemical in the European Union. They also found the scientific rationale for these regulations to be outside the scope of the CIR.

From the April 2017 CIR Post-meeting Announcement:

"The Expert Panel issued a final report with the conclusion that Hydrofluorocarbon 152a is safe in cosmetics in the present practices of use and concentration described in the safety assessment. This ingredient is a gas (at standard temperature and pressure) that functions as a propellant and is used at concentrations < 80% in hair sprays and 35% in underarm deodorants. . . The Panel found the overall safety profile of this ingredient to be favorable, and concluded that it is safe for use in cosmetics.

The Panel noted that the European Union has issued regulations restricting the use of fluorinated gases in personal care and household products. The regulations are directed toward protection of the global environment, which falls outside of the Panel's purview of personal use safety."²⁹ (emphasis added)

B. Dismissal of Occupational Safety Hazards of Cosmetics

Example: Phthalates

Occasionally, the CIR will calculate margins of safety for the use of a cosmetic ingredient to substantiate their conclusions of safety. These calculations, however, are always based on expected consumer use of cosmetics, and do not take into account the significantly higher exposures experienced by salon workers.

In 2005, the CIR published their safety determination for phthalates, in which they calculated a margin of safety. The estimated exposure to phthalates was created by summing the expected exposures to phthalates from a single application of nail polish, a single use of hair spray, a single use of deodorant and a single use of perfume. This calculation both ignores and significantly underestimates the potential exposures experienced by a salon worker using many of these products multiple times a day. The CIR's determination of safety for phthalates therefore excludes any assessment of the safety of exposure to salon workers.³⁰

Example: Hair Dye Epidemiology

The CIR publishes a resource document on epidemiological studies of the health hazards of hair dye. In this report, the CIR concludes that:

“The CIR Expert Panel determined that the available hair dye epidemiology data do not provide sufficient evidence for a causal relationship between personal hair dye use and cancer, based on the lack of strength of the associations and inconsistency of the findings.”

Again, although the greatest exposure and risk of hair dye falls with salon workers who may be applying these products daily, these occupational concerns are dismissed by the CIR.

Specifically, the hair dye epidemiology report states:

*“The CIR Expert Panel reviews selected, new epidemiological studies addressing the personal use of hair dyes as these studies become available. Table 1 summarizes these studies specifically addressing bladder cancer, lymphoma, and leukemia. **Occupation as a hairdressers, barber, or cosmetologist involves exposures to multiple products used during work, making it difficult to use the results of such studies to inform the assessment of the risk, if any, associated specifically with hair dyes. Accordingly, such studies are not summarized here.**”³¹*
(emphasis added)

One result of the narrow scope of the CIR is that cosmetic ingredients that are known to cause harm to waterways, affect the global environment, cause endocrine disruption in wildlife and cause cancer or other harms to salon workers may well be ruled as “safe” in cosmetics by the CIR. A “safe as used” conclusion from the CIR would therefore be highly misleading for consumers, workers, manufacturers, and regulators alike who are equally interested in these broader impacts of cosmetic chemicals.

Overly Broad Conclusions on Inhalation Hazards

Inhalation is an important exposure pathway to consider in assessing the safety of cosmetic ingredients. Cosmetic products that are sprayed, as well as cosmetics in powder form, present the most significant potential for inhalation. In some cases, the CIR considers cosmetic ingredients that have known respiratory hazards. To handle these concerns, the CIR drafted inhalation boilerplate language that could be adapted as needed to address inhalation hazards of specific ingredients. Unfortunately, the boilerplate language was written so broadly that it states the blanket assumption that particles of cosmetic ingredients are almost never small enough in diameter to be inhaled deeply enough into the lungs to cause any respiratory damage. This statement has been used in numerous CIR safety assessments to dismiss or ignore data on respiratory hazards of cosmetic ingredients by assuming that the use of any ingredient in a cosmetic product will never be deeply inhaled.

This boilerplate language is based on the scientific understanding that particles with a diameter of greater than 10 µm (microns) are too large to be inhaled deeply into the lungs. Large particles, therefore, can be cleaned out by the respiratory system, and permanent damage can be avoided. An understanding of the range of particle sizes emitted by a cosmetic product is key to assessing the inhalation safety. Unfortunately, the CIR boilerplate language is based on minimal and outdated data on particle sizes emitted from cosmetic products.

For spray products, the commonly used CIR boilerplate language states:

“The CIR Expert Panel noted that, in practice, 95% to 99 % of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters greater than 10 µm. Thus, most aerosol droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions of the respiratory tract and would not be respirable to any appreciable amount.”³²

This statement is based on data from a single 2006 study which measured particle sizes from several household spray products.³³ While the data from this study indicate that 95% -99% of droplets/particles from hairsprays had diameters greater than 10 µm, the study also tested deodorant sprays, for which only 50% of droplets/particles had diameters greater than 10 µm. No other types of cosmetic spray products were tested, making it difficult to know how frequently cosmetic sprays actually have large proportions of inhalable particles. Nevertheless, the CIR consistently uses the claim that 95%-99% of droplets/particles of all cosmetic sprays are not respirable, thus ignoring the data on deodorant sprays and dismissing the very real potential of respiratory harm. Even more surprising, is that for some cosmetic ingredients, specific information about the average particle sizes used in cosmetics was provided to the CIR by manufacturers. Even in these cases when the CIR is provided with data that indicated a large proportion of the particles are small (i.e. smaller than 10 µm), the safety assessment has still used the contradictory boilerplate language indicating that 95-99% of particles are not respirable to reach a conclusion of safety.

Example: Polyurethanes

The CIR safety assessment of polyurethanes clearly indicates that these ingredients can be respiratory hazards. For example, the safety assessment clearly states the links between polyurethane exposures and occupational asthma:

“The ingredients in this report are copolymers, each of which is synthesized, in part, from isocyanate analogs. Exposure to diisocyanates (monomers of the polymers in this report) in the work place is one of the leading causes of occupational asthma.”³⁴

The CIR safety assessment includes little information on particle size of polyurethanes, with the exception of a single ingredient Polyurethane-14, in which unpublished data provided to the Personal Care Products Council stated that the particle size of Polyurethane-14 was reported to be 1.9 µm by one supplier. This is clearly smaller than the 10 µm level of concern, indicating that Polyurethane-14 particle could pose an inhalation hazard. In addition to the data on particle size, the safety assessment further confirmed the inhalation hazards of Polyurethane-14 with a rat study indicating that exposure resulted in increased lung weight and lung damage.

"The increased lung weights were considered an effect of exposure to the test material [Polyurethane-14] and correlated with the increased incidence and severity of alveolar histiocytosis."

The safety assessment also reported that Polyurethane-14 was one of several polyurethanes reported to be used in cosmetic spray products.

In the final safety assessment report, however, the CIR came to the surprising conclusion that inhalation of polyurethanes in cosmetics would not pose an inhalation safety concern. They based their decision on their belief that the particle size of a cosmetic spray product would likely be larger than the particle size of any single ingredient due to agglomeration. No data or studies on the potential for particle agglomeration were cited in the report or mentioned in the CIRs discussion. The final conclusion stated:

"The Panel believes that the sizes of a substantial majority of the particles of these ingredients, as manufactured, are larger than the respirable range and/or aggregate and agglomerate to form much larger particles in formulation. Thus, the adverse effects reported using high doses of respirable particles in the inhalation studies do not indicate risks posed by use in cosmetics...The Panel noted that droplets/particles from cosmetic products would not be respirable to any appreciable amount."³⁵

While the CIR boilerplate language acknowledges the potential for inhalation of powder products, it does not provide any data indicating the average particle sizes of cosmetic powders. Instead, the document concludes that particle sizes of cosmetic powders are simply too difficult to measure accurately and defers to the data on cosmetic sprays as a proxy. Advances in particle size measurement technology in recent years have been significant, especially given the advance of nanotechnology. Particle size measurement using aerodynamic and scanning mobility particle sizers (APS, SMPS) as well as particle characterization using transmission electron microscopy (TEM) is fairly common in current research.

Example: Talc

Talc is an ingredient used in many cosmetic powders. The CIR safety assessment of talc³⁶ discusses the many potential respiratory hazards of talc exposure such as,

"Human pulmonary effects of chronic occupational inhalation of talc include diffuse interstitial fibrosis and progressive massive fibrosis (often called complicated pneumoconiosis)."

"Studies have also examined whether the inhalation of cosmetic-grade talc is associated with respiratory tract cancers...an inhalation study performed by the NTP using non-asbestiform, cosmetic-grade talc concluded that there was some evidence of carcinogenic activity in male rats and clear evidence in female rats..."

The CIR safety assessment also discusses the particle sizes typically seen in cosmetic talc.

"The particle size of talc raw material varies widely by product type and by manufacturer, although typical cosmetic talcs are reported to have average particle sizes ranging between 4 and 15 μm when measured by sedimentation method."

And in one part of the safety assessment the CIR discusses a comparison on "micronized talc" versus "cosmetic talc" stating:

"Another comment paper discussed the use of micronized talc in the NTP study, which resulted in a significantly reduced particle size compared to cosmetic talc, i.e., 2.7-3.2 μm instead of 6.0-6.9 μm ."

However, despite the information that talc particles used in cosmetics are largely in respirable range (i.e. $<10 \mu\text{m}$) with estimated particle size ranges of 4-15 μm and 6.0-6.9 μm , the CIR used the aerosol boilerplate language to come to the contradictory conclusion that most particles incidentally inhaled would not be to any appreciable amount.

"Products containing talc may be applied to baby skin, used in products that could be incidentally ingested, or used near the eye area or mucous membranes. Additionally, talc is used in cosmetic sprays and powders; for example, talc is reported to be used in face powders at 100%, baby powders at 99%, aerosol make-up bases at up to 35%, and in aerosol deodorants at up to 30%. (Talc is not used in extremely high concentrations in spray or aerosol products because talc clogs the nozzle.) These products could possibly be inhaled. In practice, 95 to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters $>10 \mu\text{m}$. Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount."

As a result of the frequent use of this boilerplate language, numerous safety assessments of cosmetic ingredients conducted by the CIR have categorically ignored the potential for inhalation toxicity.

Inadequate Assessment of Data Gaps:

Data gaps in science are a major problem in the assessment of chemicals. For many chemicals currently on the market, there is simply a lack of research and scientific studies on basic health outcomes. The CIR, unfortunately, has a history of erroneously assuming that data gaps are equivalent to a lack of health effects. If no cancer studies have even been conducted on a chemical, one cannot assume that the chemical is not carcinogenic. Similarly, a chemical for which there is very little data of any kind, should lead to a request for the needed data, rather than a blanket assurance of safety.

Example: Quaternium-15

Quaternium-15 is a controversial preservative, commonly used in cosmetics, that is a formaldehyde-releaser. Given that formaldehyde is a known carcinogen, there is valid concern about the potential carcinogenicity of formaldehyde releasing chemicals. Apparently, no cancer studies on Quaternium-15 have ever been conducted. The CIR safety assessment of Quaternium-15 published in 2010 does not address the concern, and in fact does not mention cancer or carcinogenicity at all. There is no mention of the data gap or any rationale for dismissing cancer concerns. The CIR concluded that “Quaternium-15 is safe as a cosmetic ingredient in the practices of use...” without ever addressing the potential risk of cancer.³⁷

Example: DMDM Hydantoin, Imidazolidinyl Urea, Diazolidinyl Urea

The CIR treated the safety assessments of these three formaldehyde-releasing preservatives similarly. None of the safety assessments mention cancer as a potential endpoint, and no mention is ever made of the data gap (i.e. lack of any cancer studies). The safety assessments conducted for these three chemicals are decades old. The CIR published their review of DMDM hydantoin in 1988; imidazolidinyl urea in 1980 and diazolidinyl urea in 1990.^{38, 39, 40} All three chemicals were re-considered by the CIR in later years, but the cancer data gap was still not addressed or mentioned and the CIR determined there was no reason to re-open any of the safety reviews and reaffirmed their conclusions of safety. These decisions were made despite the fact that the CIR considered and documented the studies that did exist suggest that both diazolidinyl urea and DMDM hydantoin are mutagenic and imidazolidinyl urea is fetotoxic.^{41, 42}

Example: Polymerized Tetramethylcyclotetrasiloxanes

More recently, the CIR has adopted a new standard report format for their safety assessments which includes prompts to seek studies on all relevant healthpoints. This newer format results in language included in safety assessments to acknowledge where data gaps exist. The extent of data gaps, however, do not necessarily deter the CIR from coming to a conclusion of safety. As exemplified by the 2016 safety assessment of polymerized tetramethylcyclotetrasiloxanes. In this safety assessment, the CIR reported that there was almost no safety data on these chemicals available at all. Specifically, the safety assessment states:

“Absorption, Distribution, Metabolism, and Excretion

Data on the absorption, distribution, metabolism, and excretion of polymerized tetramethylcyclotetrasiloxanes were not found in the published literature and no unpublished data were provided.

Acute Toxicity

Data on the acute toxicity of polymerized tetramethylcyclotetrasiloxanes were not found in the published literature and no unpublished data were provided.

Repeated Dose Toxicity

Data on the repeated dose toxicity of polymerized tetramethylcyclotetrasiloxanes were not found in the published literature and no unpublished data were provided.

Reproductive and developmental toxicity

Data on reproductive and developmental toxicity of polymerized tetramethylcyclotetrasiloxanes were not found in the published literature and no unpublished data were provided.

Genotoxicity

Data on the genotoxicity of polymerized tetramethylcyclotetrasiloxanes were not found in the published literature and no unpublished data were provided.

Carcinogenicity

Data on the carcinogenicity of polymerized tetramethylcyclotetrasiloxanes were not found in the published literature and no unpublished data were provided.

Irritation and Sensitization

Data on dermal or ocular irritation of polymerized tetramethylcyclotetrasiloxanes were not found in the published literature and no unpublished data were provided.”⁴³

It appears that even the representative from the FDA that attends CIR meetings (but has no voting power) brought the lack of data to the CIR's attention:

“DR. SADRIEH: I just wanted to, for the record, indicate that there is no data on acute tox and the dermal penetration, gene tox, repro tox for these ingredients. That's it.

DR. SHANK: They are very small molecules.

DR. SADRIEH: That's fine. I'm just saying there's no data for it.”⁴⁴

Despite the utter lack of data on these chemicals, the CIR concluded that these chemicals were safe as used in cosmetics.⁴⁵

CONCLUSIONS AND RECOMMENDATIONS

This report highlights four ways in which the CIR has significantly underestimated or dismissed potential health and environmental hazards of cosmetic ingredients. Reliance on the CIR assessments to determine safety could lead manufacturers to use cosmetic ingredients which are in fact unsafe. Moving forward, cosmetic manufacturers and legislators alike need to establish alternative processes for determining the safety and health of cosmetic products which include the following key features:

- Transparency of both the science and process used to make safety determinations
- Assessment of impacts on a broad scope of health and environmental outcomes, including cumulative impacts
- Consideration of vulnerable populations including pregnant women, children and workers
- Opportunity for public involvement and input in governmental deliberation and decision-making
- Precautionary approach to acknowledge and manage data gaps and uncertainty in the science

REFERENCES

1. Cosmetic Ingredient Review (2010) Cosmetic Ingredient Review Procedures, October 2010. Available at: <https://www.cir-safety.org/about>
2. Cosmetic Ingredient Review (2010) Cosmetic Ingredient Review Procedures, October 2010. Available at: <https://www.cir-safety.org/about>
3. Personal Care Products Council (2007) Consumer Commitment Code. Available at: <https://www.personalcarecouncil.org/about-us/personal-care-products-council-consumer-commitment-code>
4. Cramer DW, Welch WR, Scully RE and Wojciechowski CA. (1982) Ovarian cancer and talc: a case-control study. *Cancer*. 1982 Jul 15;50(2):372-6
5. Cook LS1, Kamb ML and Weiss NS (1997) Perineal powder exposure and the risk of ovarian cancer. *Am J Epidemiol*. 1997 Mar 1;145(5):459-65.
6. Penninkilampi R and Eslick GD. (2018) Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis. *Epidemiology*. 2018 Jan;29(1):41-49. 2018.
7. Gordon RE, Fitzgerald S and Millette J. (2014) Asbestos in commercial cosmetic talcum powder as a cause of mesothelioma in women. *Int J Occup Environ Health*. 2014 Oct;20(4):318-32.
8. Finkelstein MM (2012) Malignant mesothelioma incidence among talc miners and millers in New York State. *Am J Ind Med*. 2012 Oct;55(10):863-8. 2012.
9. Miller A, Teirstein AS, Bader ME, Bader RA and Selikoff IJ. (1971) Talc pneumoconiosis. Significance of sublight microscopic mineral particles. *Am J Med*. 1971;50:395-402.
10. Ong TH and Takano A (2012) Severe endobronchitis and airway stricture caused by inhalation of cosmetic talc. *Chest*. 2012 Aug;142(2):511-513. (2012)
11. McEwen G (2002) Letter from CTFA to Dr. Kenneth Olden, Director of National Toxicology program regarding toxicity of talc. March 18 2002. Available at: <https://ntp.niehs.nih.gov/ntp/newhomero/roc12/mcewen-09-13-04.pdf>

REFERENCES continued

12. Meta-Analysis Research Group (2015) What We've Done. https://web.archive.org/web/20150221022012/http://metaanalysisgroup.com/What_We_ve_Done.html
13. Key arguments expressed by the PCPC, their consultants and the CIR were a) talc does not contain asbestos; and b) the biological mechanism for distributing talc from the perineum to the ovaries is unexplained. These arguments were made despite the fact that studies did detect asbestos in some talc samples, and talc particles have been found to be embedded in ovarian tumors.
14. Cosmetic Ingredient Review (2012) Transcript of CIR meeting December 10, 2012 Available at <https://www.cir-safety.org/sites/default/files/121012-CIR-MAIN.pdf>
15. Cosmetic Ingredient Review (2012) Transcript of CIR meeting, December 10, 2012 Available at: <https://www.cir-safety.org/sites/default/files/121012-CIR-BREAK-OUT.pdf>
16. Levin M (2015) Talc-Ovarian Cancer Link Sparks Growing Legal Battle. Fair Warning. Available at: <https://www.fairwarning.org/2015/04/talc-and-ovarian-cancer/>
17. Cosmetic Ingredient Review (2015) Safety Assessment of Talc as Used in Cosmetics. International Journal of Toxicology. 34 (Suppl.1): 66S-129S. 2015
18. OEHHA (2012) Notice of Intent to List: Benzophenone, Coconut oil diethanolamine condensate (cocamide diethanolamine), Diethanolamine and 2-Methylimidazole as Known to the State to Cause Cancer. January 20, 2012. <https://oehha.ca.gov/proposition-65/crn/notice-intent-list-benzophenone-coconut-oil-diethanolamine-condensate-cocamide>
19. NTP (2013) Nominations to the Report on Carcinogens; Request for Information. Federal Register Vol. 78, No. 183, September 20, 2013. https://ntp.niehs.nih.gov/ntp/pressctr/frn/2013/78frn183roc20130920_hmt.pdf
20. Morrison Foerster (2012) Comments on behalf of the Personal Care Products Council on Notice of Intent to List Diethanolamine ("DEA") and Cocamide DEA. April 6, 2012. Available at: <https://oehha.ca.gov/media/downloads/proposition-65/crn/comments/ext4lcmcorash.pdf>
21. Personal Care Products Council (2013) Comments regarding Nominations of the Report on Carcinogens: Request for Information (78 Federal Register 57868) October 16, 2013. Available at: https://ntp.niehs.nih.gov/ntp/roc/nominations/2013/publiccomm/loretz20131016_508.pdf
22. Cosmetic Ingredient Review (2013) Safety Assessment of Diethanolamides as Used in Cosmetics. International Journal of Toxicology. 32 (Suppl.1): 36S-58S. 2013. <https://online.personalcarecouncil.org/jsp/CIRList.jsp?id=16>
23. Chemical Watch (2016) The big preservatives crisis. Global Business Briefing, March 2016. Available at: <https://chemicalwatch.com/45723/the-big-preservatives-crisis>
24. Cosmetic Ingredient Review (2011) Cosmetic Ingredient Review Expert Panel 121st Meeting Main Session (December 12, 2011) Transcript. Available at: <https://www.cir-safety.org/sites/default/files/121211-CIR.pdf>
25. Cosmetic Ingredient Review (2011) Amended Safety Assessment of Methylisothiazolinone as Used in Cosmetics Draft Tentative Report for Panel Review. Release Date: May 16, 2014. Available at: <https://www.cir-safety.org/sites/default/files/MI.pdf>
26. Cosmetic Ingredient Review (2016) Cosmetic Ingredient Review Expert Panel 138th Meeting (April 1, 2016) Transcript. Available upon request from Cosmetic Ingredient Review.
27. Cosmetic Ingredient Review (2017) Safety Assessment of Polyaminopropyl Biguanide (polyhexamethylene biguanide hydrochloride) as Used in Cosmetics. Draft Tentative Report for Panel Review Release Date: August 18, 2017. Available at: <https://www.cir-safety.org/sites/default/files/PolyaminopropylBiguanide.pdf>
28. Cosmetic Ingredient Review (2015) Cosmetic Ingredient Review Expert Panel 135th Meeting (June 15-16, 2015) Post meeting announcement. Available at: <https://www.cir-safety.org/sites/default/files/062015PMA-v3.pdf>
29. Cosmetic Ingredient Review (2017) Cosmetic Ingredient Review Expert Panel 142nd Meeting (April 10-11, 2017) Post meeting announcement. Available at: <https://www.cir-safety.org/sites/default/files/PMA042017.pdf>
30. Cosmetic Ingredient Review (2005) Annual Review of Cosmetic Ingredient Safety Assessments 2002/2003. International Journal of Toxicology. 22 (Suppl.1): 1-102. 2005.
31. Cosmetic Ingredient Review (2014) Hair dye epidemiology. Available at: <http://www.cir-safety.org/sites/default/files/hairdyeepidemiology-2014.pdf>
32. Cosmetic Ingredient Review (2012) CIR Precedents. Aerosols. September 2012. Available at: https://www.cir-safety.org/sites/default/files/aeroso092012rep_0.pdf
33. Bremmer HJ, Prud'homme de Lodder LCH, and van Engelen JGM. (2006) Cosmetics Fact Sheet: To assess the risks for the consumer; Updated version for ConsExpo 4. 2006. Report No. RIVM 320104001/2006. pp. 1-77. Available at: <http://www.rivm.nl/bibliotheek/rapporten/320104001.pdf>
34. Cosmetic Ingredient Review (2017) Safety Assessment of Polyurethanes as Used in Cosmetics. Final Report, October 13, 2017.
35. Cosmetic Ingredient Review (2017) Safety Assessment of Polyurethanes as Used in Cosmetics. Final Report, October 13, 2017.
36. Cosmetic Ingredient Review (2015) Safety Assessment of Talc as Used in Cosmetics. International Journal of Toxicology. 34 (Suppl.1): 66S-129S. 2015.
37. Becker LC, Bergfeld WF, Belsito DV, Klaassen CD, Hill R, Leibler D, Marks JG, Shank RC, Slaga TJ, Snyder PW and Andersen FA (2010) Final Report of the Amended Safety Assessment of Quaternium-15 as Used in Cosmetics. International Journal of Toxicology 2010 29: 98S
38. Cosmetic Ingredient Review (1988) Final Report on the Safety Assessment of DMDM Hydantoin. Journal of the American College of Toxicology. Volume 7, Number 3, 1988.
39. Cosmetic Ingredient Review (1980) Final Report on the Safety Assessment of Imidazolidinyl Urea. Journal of Environmental Pathology and Toxicology. Vol. 4 (4), 133-146 1980.
40. Cosmetic Ingredient Review (1990) Final Report on the Safety Assessment of Diazolidinyl Urea. Journal of the American College of Toxicology. Volume 9, Number 2, 1990.
41. Cosmetic Ingredient Review (2003) Annual Review of Cosmetic Ingredient Safety Assessments 2001/2002. International Journal of Toxicology. 22 (Suppl.1): 1-35. 2003.
42. Cosmetic Ingredient Review (2008) Annual Review of Cosmetic Ingredient Safety Assessments 2005/2006. International Journal of Toxicology. 27 (Suppl.1): 77-142. 2008.
43. Cosmetic Ingredient Review (2016) Safety Assessment of Polymerized Tetramethylcyclotetrasiloxanes as Used in Cosmetics. Draft Final Report for Panel Review, March 7, 2016.
44. Cosmetic Ingredient Review (2016) Safety Assessment of Polymerized Tetramethylcyclotetrasiloxanes as Used in Cosmetics. Draft Final Report for Panel Review, March 7, 2016. https://www.cir-safety.org/sites/default/files/cyclotetrasiloxanes_0.pdf
45. Cosmetic Ingredient Review (2016) Safety Assessment of Polymerized Tetramethylcyclotetrasiloxanes as Used in Cosmetics. Final Report, September 21, 2016.