

**citizen enforcers start the new  
year with a bang**

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# Recent Notices of Violation January /February 2019

By LisaLisa | citizen enforcers start the new year with a bang

Proposition 65 enforcers have kicked off the new year with a bang. Citizen enforcers (AKA bounty hunters) have issued 264 new notices of violation in January 2019, and they have only just begun to rack up settlements related to notices of violation. It is evident that recent trends in citizen enforcement continue to target products containing phthalates and lead and lead compounds.

There has been more activity concerning alcoholic beverages than in recent years as a result of modifications made to alcoholic beverage warnings near the end of last year.

Citizen enforcers have concentrated their efforts in household products found in big box stores and discount dollar stores recently. Certain food products such as raw cacao containing cadmium and clam meat that allegedly contains lead were also issued notices of violation. Marijuana entrepreneurs can expect to be targeted by Prop 65 citizen enforcers this year and beyond. It is a good time to carefully check that your product warnings comply with the latest warning language for their application.



*Alcohol Warning*

# OEHHA to Task the DART-IC with Cannabis Toxicity Evaluation

By LisaLisa | citizen enforcers start the new year with a bang

California's Office of Environmental Health Hazard Assessment (OEHHA) has engaged the state's Developmental and Reproductive Toxicant Identification Committee (DARTIC) of OEHHA's Science Advisory Board to evaluate whether certain cannabis compounds, such as (marijuana), marijuana (cannabis) smoke, cannabis extracts, and  $\Delta$ -9-Tetrahydrocannabinol (THC) has been shown to cause reproductive toxicity (developmental toxicity endpoint). Chemicals identified as reproductive toxicants by the DARTIC are added to the Proposition 65 list.

OEHHA will develop hazard identification materials on cannabis chemicals and is requesting scientific information relevant to whether they cause reproductive toxicity (developmental toxicity endpoint). The data call-in period will end at 5:00 p.m. on April 29, 2019. The committee meeting is tentatively planned for sometime in the Fall of 2019, but the date has not been announced.

The timing of the evaluation is interesting as the USDA has hinted at possibly loosening restrictions for certain cannabidiol extracts in food or dietary supplements.

The departure of Commissioner Scott Gotlieb from his post may not have much of an impact going forward. Recently Commissioner Gotlieb announced the formation of a working group to develop rules that would permit the use of certain extracts from hemp in food or dietary supplements and indicated that a public hearing was being planned to discuss how some uses of cannabidiol in food and dietary supplements might be legalized.



Dart-IC's upcoming evaluation of cannabis compounds may have a profound impact on the cannabis industry if the compounds are found to cause developmental toxicity. Such a finding would cause Cannabis providers to post "Clear and reasonable warnings along the lines of the alcohol warnings for pregnant women.

# New York Governor Andrew Coumo Introduces the Consumer Right to Know Act

By LisaLisa | citizen enforcers start the new year with a bang

Governor Andrew M. Cuomo recently announced as part of his Executive Budget a proposal that would protect New Yorkers from unknown exposure to toxic chemicals. The “Consumer Right to Know Act” would authorize the New York Department of Environmental Conservation, in consultation with the Department of Health and the Department of State, to develop regulations establishing on-package labeling requirements for designated products indicating the presence of potentially hazardous chemicals, including carcinogens. Video of the Governor announcing this proposal is available on YouTube [here](#).

“The more we know about our exposure to chemicals, the more frightening the situation is,” Governor Cuomo said in a press conference. “Consumers have the right to know what is in the products they use, and requiring labeling on designated products will provide consumers with the information they deserve.”

According to Governor Cuomo, under this proposal, the agencies will assess the feasibility of on-package labeling and develop regulations establishing a labeling requirement for designated products, developing a list of more than 1,000 carcinogens and other chemicals that will trigger labeling requirements and identifying the types of consumer products that will be subject to the new regime.

In addition, the legislation will extend the Department of Environmental Conservation’s previously established household cleaning product disclosure requirements to cover all cleaning products sold in New York State, and it will give the Department of Health the authority to require similar disclosure for the manufacturers of personal care products like shampoo, deodorant or baby powder. Under these requirements, cleaning product and personal care product manufacturers must make certain product ingredient information publicly available on their websites and on a publicly accessible database.

Governor Cuomo said he will further direct DEC, DOH, and DOS to explore additional potential measures to empower consumers with more information.

It may just be me, but New York’s proposed legislation seems very familiar, in fact, It’s like Déjà vu all over again!

Despite the Governor’s promise of empowerment for New Yorkers seeking safe products, the proposal did not mention any type of enforcement mechanism to penalize manufacturers and distributors that fail to comply with the proposed regulations—a very convenient omission to say the least.

Although it’s unlikely that New York would adopt a California style bounty hunter enforcement model, the state would have to create some sort of enforcement mechanism to keep the non-compliant in line. It will be



very interesting to see what Albany comes up with further down the line.

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# ACC Appeals California Spray Foam Priority Product Designation

By LisaLisa | citizen enforcers start the new year with a bang

ACC appeals California spray foam priority product designation  
Methylene chloride paint strippers added to SCP program

The American Chemistry Council has filed an appeal to reverse a determination made by the California Department of Toxic Substances Control (DTSC) to designate spray polyurethane foam (SPF) systems as a priority product under the Safer Consumer Products program.

In a letter dated January 2, 2019 to the director of the DTSC, the ACC initiated the formal appeal process, reiterating a prior request for the agency to withdraw the designation.

Under the SCP scheme, manufacturers of designated product-substance pairs are required to either complete an alternatives analysis to determine if a safer replacement is available or to reformulate to avoid the substance's use.

Last year California designated SPF systems containing unreacted methylene diphenyl diisocyanates (MDI)



its second priority product. In 2017 the agency had announced children's foam padded sleeping products containing flame retardants TDCPP or TCEP as the first product. However, as the marketplace had already phased the substances' use out, this resulted in no notifications.

The designation of SPF systems has, however, been delayed by industry pushback. Last May, the ACC filed an informal protest regarding the listing. This temporarily halted the original September notification deadline.

The ACC argued that the DTSC should withdraw it because SPF systems do not meet the criteria for inclusion in the program. And it said the department had not adequately demonstrated the potential for significant or widespread adverse effect from their use.

In a September meeting with DTSC, the ACC proposed the agency enter into an enforceable consent agreement (ECA) instead to address concerns with the product.

DTSC urged the ACC to "accept the results of this comprehensive, objective regulatory process, and comply with the requirements"

But in December, the DTSC rejected the request and said it was not permitted under the SCP Regulation to enter into an ECA. In its response, it urged the ACC to "accept the results of this comprehensive, objective regulatory process, and comply with the requirements."

This response prompted the ACC into filing their appeal which also reiterated the organization's request for the DTSC to withdraw the priority product designation for SPF systems and to reconsider its view that it lacks the authority to enter into an ECA.

Entering an agreement, it said, "would be the most time- and cost-efficient solution, would allow the public an opportunity to participate through public comments and public hearings, and could produce an alternatives analysis as one possible outcome."

A spokesman for ACC said it is offering a 'reasonable and responsible path forward that helps the state achieve its public health objectives in a faster, simpler, and more collaborative manner'

The requirement for SPF manufacturers to notify the DTSC has been paused during the informal dispute process. The formal process will result in an additional stay, a spokesperson for the agency said.

#### Methylene chloride paint strippers

The ACC's move on SPF came shortly after the state named methylene chloride to paint strippers the program's third priority product, with their designation taking effect from 1 January. Manufacturers that sell these products in California must notify the state by 4 March, and then either begin the alternatives analysis process or reformulate.

The DTSC said that it took the step, in part, due to the US EPA's failure to finalize a 2017 TSCA proposal to ban the products, which have been linked to dozens of deaths in recent years. The EPA signaled last May that it would finalize the ban "shortly", but it has yet to do so.

In the meantime, NGOs have been putting pressure on retailers to halt the products' sales, with many - including Lowe's, Walmart and Home Depot - committing to doing so.

DTSC has also announced plans to address an alternative product - paint and varnish strippers containing N-methylpyrrolidone (NMP) by naming it a future priority product.

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# In an about Face, Retailer Claire's Decides to Recall Asbestos Containing Cosmetic Products

By LisaLisa | citizen enforcers start the new year with a bang

Retailer Claire's is recalling three makeup products after federal regulators warned the products might contain asbestos.

Last week, the U.S. Food and Drug Administration said product samples tested positive for asbestos but that Claire's refused to recall any products that might still be in homes. The retailer at the time disputed the test results but a company spokesman said it removed the products from stores.

Now, the company has decided that it will also recall all of the products, which were sold between 2016 and this month. A Claire's representative wasn't available for comment about how it will recall the products.

Asbestos is a toxic substance that can get into the lung tissue and over time can cause a particularly aggressive form of cancer, known as Meselthileoma. The greatest risk for contracting the disease is to people with frequent, long-term exposure, such as workers that remediate asbestos. The FDA said it's not aware of anyone being sickened by the makeup products.

Currently, Cosmetics don't have to be reviewed by the FDA before they're sold. However, congressional legislation to grant additional oversight to the agency may cause the FDA to promulgate regulations to oversee product safety for cosmetics and personal care products.

Asbestos is among the first ten substances to go through a risk assessment pursuant to the revised TSCA regulations. The Risk assessment is expected to be completed next month.

Last year Claire's recalled 17 products containing asbestos in children's cosmetics products. Exposure to asbestos is estimated to claim the lives of 15,000 Americans every year. Currently, there is no law



regulating the sale of products contaminated by asbestos.

# OEHHA Adopts ‘No Significant Risk Level’ (NSRL) for Bromodichloroacetic Acid

By LisaLisa | citizen enforcers start the new year with a bang



*Chemistry laboratory glassware with color liquids in them*

California’s Office of Environmental Health Hazard Assessment (OEHHA) has announced the “Amendment to Section 25705 No Significant Risk Level (NSRL) for Bromodichloroacetic Acid (BDCAA).” The change confirms that the NSRL for bromodichloroacetic acid is 0.95 micrograms per day.

Bromodichloroacetic acid is a water-disinfectant byproduct. It was listed as a carcinogen under Prop 65 on July 29, 2016 based on a 2015 report by the National Toxicology Program (NTP).

The OEHHA listed BDCAA as a carcinogen based on criteria verified by an authoritative body. The supporting documents used as the basis for the administrative listing of bromodichloroacetic acid was included in the agency’s “Notice of Intent to List Bromodichloroacetic Acid” published on its website as well as in the California Regulatory Notice Register in May 2016.

The notice also invited public comments during the period that ended on June 27, 2016. However, OEHHA did not receive any public comments on bromodichloroacetic acid.

Bromodichloroacetic acid is a byproduct of water treatment processes using chlorine and other halogenated oxidants, according to the NTP report.

Bromodichloroacetic acid and other water disinfection byproducts increase the possibility of cancer and may cause fetal growth and development problems during pregnancy.

California’s Proposition 65 requires manufacturers and retailers to provide the required warnings to consumers and workers using or exposed to their products that used chemicals listed under the system. However, setting an NSRL provides a ‘safe harbor’ level. A Prop 65 warning is not required for any product containing the listed chemical below the “safe harbor level. The new Safe Harbor level will take effect on April 1, 2019.

# DOD Proposal on Trichloroethylene Exposure Levels to be reviewed by the National Academies of Science

By LisaLisa | citizen enforcers start the new year with a bang

## DOD Proposal on Trichloroethylene Exposure Levels to be reviewed by the National Academies of Science.

A proposed approach put forward by the US Department of Defense for developing an occupational exposure



level for trichloroethylene National Academies of Sciences (NAS).

(TCE) will come under the scrutiny of the

The federal scientific body (NAS) has appointed a provisional committee to examine the DOD proposal, which also includes developing a TCE cancer slope factor, to estimate the risk of cancer for situations in which vapor intrusion is the exposure pathway.

NAS said in a statement that important elements of the committee's review will include:

- the data selection process;
- evidence synthesis;
- dose-response assessments;
- the use of physiologically based pharmacokinetic models; and other factors
- other factors associated with calculating a scientifically sound safety level

The eight-member committee is provisional, pending a 20-day consultation period that ends on February 14, 2019.

TCE is one of the first ten existing chemicals to undergo risk evaluations under the Revised TSCA regulations.

TCE may also be subject to [a pair of proposed TSCA section 6 rules](#). Section 6 gives the EPA power to ban or restrict a chemical if it finds it presents an unreasonable risk to human health or the environment. This unreasonable risk requirement is significant because recent history suggests that TCE vapor may pose an unreasonable risk to human health.

In 2016 TCE vapor intrusion in a mobile home park in El Cajon California, that was located within 100 yards of a shuttered defense plant appears to have caused the deaths of at least two residents of the mobile home park.

The rules proposed under Title 6 of the revised TSCA regulations were proposed in the final days of the Obama administration, with the intention of banning the use of TCE in vapor degreasing applications, and as an aerosol degreaser and spot cleaner. However, it is unclear whether the agency will opt to shelve the TCE proposals.

# California Names Nail Products Containing Toluene as a Priority Product

By LisaLisa | citizen enforcers start the new year with a bang

California's Department of Toxic Substances Control has proposed listing nail products containing toluene as its latest priority product under its Safer Consumer Products program.

If adopted, the designation will prompt manufacturers either to phase out the substance's use in that application or to undertake an alternatives analysis if they want to continue serving the California market.

Toluene is used as a solvent in a variety of nail products, including polishes, hardeners, and thinners. But it has been linked with damage to the nervous system and respiratory tract, as well as developmental effects such as low birthweight. DTSC said this presents a concern for the states more than 130,000 nail salon workers, many of whom are women of childbearing age.

Meredith Williams, acting director of DTSC, said industry "has known for a long time that toluene is a problematic chemical in these products."

"Responsible manufacturers have moved away from it. We want to make sure that others do the same," Williams added.

As a first step, DTSC has released a draft technical report outlining the scientific basis of the proposal. The agency has opened a comment period on the draft will be open until March 15.

DTSC will also host a public workshop to receive comments on March 13. The technical report will then be updated, based on the comments, and submitted to an independent scientific review panel.

Toluene is also the subject of recent state-level legislation in states like New Jersey and New York, which are considering banning its use in nail products, alongside dibutyl phthalate (DBP) and formaldehyde.

In 2016, the DTSC sought feedback on this so-called "toxic trio" of substances. But in its technical report, it said that most nail product manufacturers have largely phased out formaldehyde and DBP, while some are continuing to use toluene.

## Safer Consumer Products Program

California's Safer Consumer Products program identifies products that contain potentially harmful chemicals and has manufacturers look for potential replacements via alternatives analyses. The program took effect in 2013 as a consequence of California's green chemistry laws, passed in 2008.

Other products that have been adopted as SCP priorities include:

- paint or varnish paint strippers containing methylene chloride;
- spray polyurethane foam with unreacted MDI; and
- children's foam-padded sleeping products with the flame retardants TDCPP or TCEP.

Aside from nail products containing toluene, other proposed priority products include:

- perfluoroalkyl and polyfluoroalkyl substances (PFASs) in carpets and rugs;
- laundry detergents containing the surfactants nonylphenol ethoxylates (NPEs); and
- paint and varnish strippers and graffiti removers containing N-methylpyrrolidone (NMP).



Davide Rogowski, AOL

# CIC to Determine Whether Acetaminophen is Carcinogenic

By LisaLisa | citizen enforcers start the new year with a bang



California's Office of Environmental Health Hazard Assessment (OEHHA) has announced that the state's Carcinogen Identification Committee (CIC) of OEHHA's Science Advisory Board will that the expert panel will consider whether acetaminophen should be added to the state's list of Proposition 65 carcinogens.

Acetaminophen was selected for this review when the CIC expert committee added the The Carcinogen Identification Committee (CIC) of OEHHA's Science Advisory Board serves as the state's qualified experts and renders an opinion about whether a candidate chemical has been clearly shown to cause cancer. The chemicals identified as carcinogens by the CIC are added to the Proposition 65 list.

OEHHA has selected acetaminophen for the CIC's review for possible listing under Proposition 65. The agency is initiating the development of hazard identification materials pertaining to this chemical.

According to a 2011 study published in the Journal of Clinical Oncology, Aspirin and ibuprofen did not increase the risk of lymphoma, however, their findings suggested these findings applied only for acetaminophen. Aspirin and ibuprofen did not increase this risk, according to the study. published on May 10, 2011

Chemical Selected for Preparation of Cancer Hazard Identification Materials.

The review that the CIC expert panel will look at other scientific evidence that may be more recent than the Journal of Clinical Oncology's findings.

## **Chemical Acetaminophen**

### **CAS No.**

**Acetaminophen 103-90-2**

### **103-90-2**

OEHHA is soliciting public comments to provide information relevant to the assessment of the evidence of carcinogenicity for acetaminophen. Relevant information includes but is not limited to:

Cancer bioassays

Cancer epidemiological studies  
Genotoxicity testing

Other pertinent data on:

Pharmacokinetics

Biomarkers; and

Effects on biochemical and physiological processes in humans

Interested parties wishing to provide pertinent information should submit it on or before April 29, 2019.

Array

OEHHA selected this chemical from those prioritized by the CIC in 2011. For details, follow this link:

<https://oehha.ca.gov/proposition-65/transcript-comment-presentation/meeting-synopsis-and-slide-presentation-carcinogen>.

Hazard identification materials for acetaminophen will be presented at a future meeting of the CIC for consideration of listing under Proposition 65. As of the release of this notice, this meeting has not been scheduled.

Hazard identification materials are made available to the public for comment prior to the CIC's consideration of the chemical for possible listing. The availability of hazard identification materials will be announced in the California Regulatory Notice Register and on OEHHA's website. Public comments received on these materials are sent to the CIC for its consideration prior to the meeting at which the chemical will be considered for listing. OEHHA announces the time, date, location, and agenda of CIC meetings in the California Regulatory Notice Register and on its website.

We encourage you to submit relevant information responsive to this request in electronic form, rather than in paper form. Comments may be submitted electronically through our website at

<https://oehha.ca.gov/comments>. Comments submitted in paper form can be mailed, faxed, or delivered in person to the addresses below:

Mailing Address:

Julian Leichthy

Office of Environmental Health Hazard Assessment

Proposition 65 Implementation Program

P.O. Box 4010, MS-12B

Sacramento, California 95812-4010

Fax: (916) 323-2265

Street Address:

1001 I Street

# Combe Strikes Back

By LisaLisa | citizen enforcers start the new year with a bang



The US FDA has put on hold its final rule that would ban the use of lead acetate as a coloring additive in hair dyes, following objections from the manufacturer of Grecian formula, Combe, International.

The proposed ban of lead acetate, which followed the agency's consideration of an April 2017 petition filed by the Environmental Defense Fund and other NGOs, was published in the Federal Register in October 2018. In it, the FDA said new data indicates there is "no longer a reasonable certainty of no harm" from the use of lead acetate in products used to gradually darken gray hair.

The FDA's plan to amend the color additive regulations were scheduled to take effect on December 3, 2018, with a one-year period of enforcement discretion to allow the hair dye industry to reformulate during the interim time.

But within the 30-day period for filing objections, personal care products company Combe International requested a formal evidentiary public hearing on the US FDA's final rule, effectively placing the rulemaking action on hold.

The FDA had intended to publish a Federal Register notice in late 2018 staying the rule, pending resolution of the objections. That action, however, has been delayed due to the partial shutdown of the federal government.

## Objections

Combe International - the manufacturer of Just for Men and Grecian Formula - said in its objections submitted on November 30, that the FDA had failed to show there is no longer a reasonable certainty of no harm for the use of lead acetate in progressive hair dyes.

Among the company's concerns was the FDA's use of what the company described as "unvalidated and novel computer analysis." The company complained that this did not appear in the NGO petition, nor was it made available during the public comment period.

Combe also claimed that the FDA had “erroneously discarded a landmark clinical study” which it had partially relied on in its original 1980 approval of the color additive in its hair dye.

“The science supports the continued safety of lead acetate in hair dye,” Combe concluded.

### **Petitioner Vehemently Disagrees**

In a blog post, the EDF’s chemicals policy director, Tom Neltner, said it was “unbelievable that a company is standing up for the use of the heavy metal in their product.”

Combe notes that it has reformulated its products to no longer include lead acetate. Neltner questioned whether a desire to reduce exposure to litigation motivated the objections.

“FDA acknowledged that the study on which the original safety decision was made in 1980 had five serious deficiencies, Mr. Neltner said. “If the company allows FDA’s ban to stand unchallenged, they are particularly vulnerable to legal challenges.”

Anthony Santini, senior vice president and general counsel for Combe, confirmed that the company no longer manufactures or distributes hair coloring products containing lead acetate.

But he said that the original formula of Grecian Formula was “safely used by loyal consumers for over five decades,” and that the FDA has “significantly misconstrued the evidence concerning lead acetate and erred in its conclusions regarding the color additive petition.”

“Combe trusts that through its objections and a formal evidentiary hearing, the record will be corrected regarding the long-time safe use of lead acetate in progressive hair dye products,” Mr. Santini added.

Neltner said his organization plans to participate in the hearing and cross-examine the company’s witnesses. “EDF and others are ready to defend FDA’s decision to get the lead out of hair dyes,” he concluded.

Grecian Formula was one of the first products to face a Proposition 65 enforcement action by the California Attorney General in the 1980s. Combe, Inc, entered into a settlement with the Office of the Attorney General requiring reformulation to eliminate the lead contained in its hair dye products.

# OEHHA Takes Steps to Finalize Proposed Coffee Regulation

By Jack Schatz | citizen enforcers start the new year with a bang

California's Office of Environmental Health Hazard Assessment (OEHHA) has taken a potentially final step toward exempting coffee from Proposition 65 warnings.

The agency had proposed in June 2018 that it intended to create a specific exemption for exposures to acrylamide and other Proposition 65-listed chemicals that are present in coffee as a result of roasting coffee beans

The regulation would establish as a matter of law that exposures to acrylamide and 14 other Proposition 65 chemicals, created when coffee beans are roasted, pose no significant risk of cancer, thereby exempting them from warnings:

- **25704. Exposures to Listed Chemicals in Coffee Posing No Significant Risk**

Exposures to listed chemicals in coffee created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer.

Public comments on the proposal closed on August 30, 2018. OEHHA has now completed its review and response to comments, including multiple submissions from the Council for Education and Research on Toxics (CERT), a Proposition 65 plaintiff.

CERT is currently locked in a Proposition 65 enforcement battle with over 60 companies that roast, distribute, or sell coffee at retail, seeking civil penalties and Proposition 65 warnings about acrylamide in coffee. CERT also brought a separate action against OEHHA, challenging the legal and scientific validity of the proposed exemption. Both cases are currently pending in Los Angeles Superior Court.

OEHHA has now completed its review and response to public comments. On January 10, 2019, OEHHA submitted the regulation — with no change to the proposed language — along with its 160-page final statement of reasons to the Office of Administrative Law (OAL) for review.

OAL has until February 19, 2019 to approve the regulation, reject it, or request further information from OEHHA.



*LA Superior Judge Elihu Berle ruled that coffee sold in California must carry a Prop 65 warning*

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CERT is currently locked in a Proposition 65 enforcement battle with over 60 companies that roast, distribute, or sell coffee at retail, seeking civil penalties and Proposition 65 warnings about acrylamide in coffee. CERT also brought a separate action against OEHHA, challenging the legal and scientific validity of the proposed exemption. Both cases are currently pending in Los Angeles Superior Court.

OEHHA has now completed its review and response to public comments. On January 10, 2019, OEHHA submitted the regulation — with no change to the proposed language — along with its 160-page final statement of reasons to the Office of Administrative Law (OAL) for review.

OAL has until February 19, 2019 to approve the regulation, reject it, or request further information from OEHHA.

# FDA Bans Lead Acetate In Hair Dyes

By Jack Schatz | citizen enforcers start the new year with a bang



The U.S. Food and Drug Administration has announced its Final Rule that bans the use of lead acetate as a hair dye ingredient.

The chemical is an active ingredient that causes gray hair to darken gradually. In 1980 lead acetate was listed by the FDA as a safe ingredient in adult hair coloring products.

However, there was a petition filed in April 2017 by the Breast Cancer Fund, EWG, Consumers Union, Environmental Defense Fund, Natural Resources Defense Council and other groups. Investigation showed that “there is no longer a reasonable certainty of no harm” from its use. The FDA reversed its previous decision that lead acetate was safe in response to this petition.

According to FDA Commissioner Scott Gottlieb, in 40 years after lead acetate was approved as a safe color additive, new information shows that the “use of lead acetate in adult hair dyes no longer meets our safety standard.” Unlike other chemicals, there is “no safe exposure level for lead” according to the U.S. Centers for Disease Control and Prevention.

The Environmental Working Group’s legislative attorney, Melanie Benesh, said that lead is a “potent neurotoxin” and is “reasonably anticipated to be a human carcinogen.”

The Environmental Defense Fund’s (EDF) chemicals policy director Tom Neltner, considered FDA’s new rule as an important step to protect the product users from continued exposure to lead.

The FDA stated in its Federal Register notice that it agrees with the EWG and the other petitioners that at this time, there is no available evidence to determine the safe level if lead acetate is used as a hair dye color additive. The agency based its conclusion on an acknowledgment of the current common agreement that that lead has no safe exposure level and the deficiencies discovered during the reevaluation of the skin absorption study done in 1980.

The FDA will give hair dye manufacturers a year from the ruling date to reformulate their products. The FDA decided to “exercise enforcement discretion” for a year because bismuth citrate is already being used as a

lead acetate alternative in some hair dye products.

The FDA considers bismuth citrate as safe if the concentration will not exceed 0.5% of the final hair dye product. During the transition period, hair dye manufacturers that are still using lead acetate will list the chemical as one of the ingredients on the label together with a warning that the product is “For external use only. Keep this product out of children’s reach.”

### **NGO petition**

In their 2017 petition, public health advocates and a number of NGOs stated that listing lead acetate as safe in 1980 resulted in significantly high levels of the chemical in hair dyes. In fact, lead concentration in hair dyes was higher than the limit set for household paints by the U.S. Consumer Product Safety Commission (CPSC).

Lead contamination from hair dye is not only through direct contact with the scalp but also from touching the combs, taps, blow dryers and other tools used to dye hair.

The FDA, through its Federal Register notice, announced that it will consider objections to the new ruling filed within the 30 day period from the date of publication.

The Office of the California Attorney General filed one of its earliest Proposition 65 Enforcement actions against, Combe Inc, the makers of Grecian Formula, based on their use of lead acetate in their hair dye products. The company subsequently reformulated their hair dye products and entered into a settlement with the Attorney General.