Minnesota RETAILERS

driving innovation, succeeding together

March 24, 2025

Chair Heintzeman, Chair Fischer, and Members of the Committee:

On behalf of Minnesota Retailers and the 1,200 storefronts we represent across the state, we urge your support for HF 737, which seeks to exempt artist paints from the 2023 Minnesota ban on products containing lead and cadmium. While the intent of the original legislation—to protect public health from the harmful effects of these substances—is commendable, its broad application has inadvertently impacted the art community by restricting essential materials.

Cadmium-based pigments have been integral to artistic expression with even the European Chemicals Agency, in 2013, recognizing that the contribution of cadmium from artist paints to environmental contamination is negligible compared to other sources. Moreover, these pigments are formulated to be insoluble, minimizing potential health risks during typical use.

The current ban has affected art supply retailers in Minnesota, limiting their ability to provide essential materials to artists and students. This restriction not only hampers artistic endeavors but also places local businesses at a competitive disadvantage and pushes some artists to purchase out-of-state.

We respectfully ask the Committee to remove the age restriction relating to paints and pastels. The vast majority of these products are purchased by adults or mature young artists. This restriction would have little impact while potentially creating unnecessary barriers for legitimate customers.

In addition to supporting the exemption for artist paints, we support the inclusion of keys, ink pens, and mechanical pencils in the exemptions. Currently, there are no commercially feasible lead-free alternatives for these other products. Because of this, retailers across the state have essentially had their entire stock of keys, pens, and mechanical pencils banned. The Minnesota Pollution Control Agency has acknowledged that transitioning to alternatives will require time.

By passing HF 737 and removing the age restriction on cadmium paints, Minnesota can continue to protect public health while addressing the practical needs of consumers and alleviate the issues created for retailers.

Thank you for your time and consideration.

Sincerely,

Bruce Nustad
bruce@mnretail.org

MEMO

March 24, 2025

To: Whom it may concern

From: Elliot Sigal, Intrinsik Corp.

Re: Submission to the Minnesota Pollution Control Agency (MPCA) on behalf of the Art & Creative Materials Institute (ACMI)

Introduction

Intrinsik is a science-based consulting firm with more than 80 employees including 8 DABTs, 6 ERTs, 10 PhDs, and an Occupational Physician. I am a Senior Toxicologist and Vice President with more than 35 years of experience, working for industry and government clients, assessing the potentials exposures and risks of for chemicals in consumer products and the environment on people and the environment.

The Arts and Creative Materials Institute (ACMI) has requested Intrinsik to comment on the potential risks of harmful exposure to public health and the environment as a result of lead and cadmium exposure from artists' supplies. Notably, the majority of modern cadmium pigments are encapsulated or bound, making them relatively insoluble and less bioavailable, resulting in a significant lower risk than raw cadmium metal.

Cadmium in Art Supplies

The cadmium (Cd) content found in art supplies while exceeding the arbitrary limit created by Minn. Stat. § 325E.3892 (the Statute) does not pose a significant health risk to children. Children's risk of exposure to cadmium from artists' supplies is de minimis, considering how oils, watercolors, acrylics, temperas, pastels, ceramic glazes, stains and pigments, both powder and liquid, are used and recognizing the controlled settings where their use is most prevalent. Any potential cadmium exposure to children from artists' materials would derive from children ingesting or mouthing materials which contain cadmium or have been contaminated with cadmium containing products. Furthermore, professional artists who overwhelmingly purchase and use these products have an appreciable understanding of the hazards involved with the materials they use on a day-to-day basis and of the proper manner to handle and dispose of these. Consequently, the use of these particular art supplies poses no appreciable health risk to people or the environment.

In order to properly evaluate the potential long term health concerns to adults and children arising from cadmium exposure from professional artists' supplies, the available scientific literature was reviewed.

The Country of Sweden proposed a regulatory restriction to the European Parliament in 2013 intended to limit the level of cadmium in artists' paints within the European Union to less than 0.1% by weight (1000 ppm) (KEMI, 2013). In response to Sweden's proposal, the European Chemicals Agency (ECHA,

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2014) conducted its own assessment regarding the effects of cadmium contamination to public health. The Committee for Risk Assessment (RAC) found that the proposed restriction was not justified.

One basic premise for the Swedish proposal was that humans are exposed to cadmium from artist paints via food. During use and brush cleaning procedures, cadmium-based artists' paint can be released to the wastewater thereby making its way to the food chain via crop uptake. The removal of cadmium input originating from artists' paints would result in an estimated reduction in average intake via food over 100 years of 0.001 µg cadmium/day (compared to baseline), which is equivalent to 0.006% of total intake via food. Although determined to become bioavailable over time (years to decades), the contribution of cadmium from artist paints to soil and thereby crops is negligible compared to other sources (0.086%).

Moreover, food safety testing on 114 glazed ceramic products was conducted on behalf of a member company by Intertek Laboratories (Lead and Cadmium Extraction from Glassware – Glazed Ceramic Surfaces; Test Method: ASTM C738−94 (Reapproved 2020) Standard Test Method for Lead and Cadmium Extracted from Glazed Ceramic Surfaces). Products included Flatware, Hollowware, Small Hollowware, Large Hollowware, Cups, Mugs and Pitcher. All extractable lead and cadmium results were <0.04 mg/L (ppm), representing passing scores under the FDA criteria.

Most pigments contain cadmium in an encapsulated form. Bioavailability is a major factor in determining the toxicity of compounds taken into a human or animal. If an ingested compound is unable to cross the wall of the gut and enter into the body, then its capacity to cause systemic toxicity is small. Therefore, bioavailability is an important factor in determining the true exposure level of chemicals in consumer products. Clapp et al. (1991)(compared the relative oral bioavailability of lead and chromium from pigment materials in both natural and encapsulated forms). Clapp et al. measured the levels of lead and chromium in the blood after 2 and 4 weeks of treatment, and after an additional 2 weeks of recovery. Blood levels were used as an index of metal uptake into the body. Exposure to the lead and chromium in the encapsulated pigment (a silica coated "Chrome Yellow" pigment where silica encapsulates the pigment particles in order to reduce release of potentially toxic lead and chromate) was much less than exposure to the toxic elements in natural forms.

Turner (2018) considered the use of cadmium pigments in consumer products. Sulfides of cadmium are extensively used by the plastics and ceramics industries as colorants. Risk assessments suggest that Cadmium sulfide pigments pose little risk to humans and the environment because of their encapsulation by the polymeric matrix and extremely low solubilities; although some concerns related to instability in the presence of acids, widespread usage and potential photo sensitivities have resulted in some re-evaluation. Cadmium pigments in ceramics are partly dissolved into a matrix medium that adheres to the product. In ceramicware, the decoration is glazed and fired at high temperature, sealing any toxic compounds and eliminating attack from food or washing solutions. Data provided by Turner (2018) supports the argument that encapsulated cadmium is not available for exposure (total Cadmium 1120-38,100 ppm vs. extractable cadmium 0.05-14.9 ppm).

Cadmium is also used as a pigment in artists' paints. Artists can be subjected to direct exposure through handling of a cadmium containing product and ingestion of the metal. Thus, artists may be subject to direct risk of exposure via contamination in the hands, clothing and/or food while resulting from the preparation and handling of cadmium containing materials. While the bioaccessibility of cadmium in paints via ingestion does not appear to have been studied directly, it would be reasonable to predict greater solubility in the more acidic environment of the human stomach than that of rainwater used to simulate leaching from agricultural soils considered by the European Chemical Agency (ECHA)(2014). However, the majority of pigments used in artists' paints, as well as other art materials, contain

cadmium in an encapsulated form, indicating that the cadmium in these products is less available for exposure. An analytical procedure capable of measuring the quantity of bioavailable cadmium in these products should be considered as an alternative to the total cadmium analysis required by the Statute. A method similar to the European requirements for food-contact ceramicware (effectively the same as that defined by the ASTM for standard test C738-94), which relate to the concentrations of Cadmium extracted by dilute acetic acid, is more appropriate for these types of products.

In its assessment, ECHA considered the release of cadmium from artists paints to the environment. Artists' paints were found to contribute 0.086% as compared to other sources. This was considered a negligible contribution. The glaze suppliers have estimated 471 lbs of cadmium (encapsulated) pigment for ceramic glazes are sold in Minnesota on an annual basis. Based on information provided above, 0.05-14.9 ppm of the encapsulated cadmium will be bioaccessible resulting in the release of up to 0.007 lbs of cadmium to the environment. If 471 lbs of cadmium are disposed of into the Littlefork River (annual flow rate of 776,908,786,176 L/year) the resultant concentration of cadmium in the water way would be 0.0041 µg/L (471 lbs/year = 214 kg/year x 0.00149% ÷ 776,908,786,176 L/year). The EPA Maximum Contaminant Level (MCL) for cadmium is 5 ppb (5 µg/L). The California Office of Environmental Health Hazard Assessment public health goal for cadmium, the level of a drinking water contaminant that does not pose a significant health risk, is 0.04 ppm (0.04 µg).

Lead in Writing Instruments

Lead is rarely used in artists' paints and pigments, and where it is used, the lead content in art materials currently complies with the Statute as well as with more stringent lead content requirements imposed by federal and other states' restrictions. As discussed above, if found in an encapsulated form, the bioavailability of lead in pigments will be greatly reduced.

The issue of lead in ballpoint pens and mechanical pencils has been previously submitted to the Minnesota Pollution Control Agency (MPCA) by the Writing Instrument Manufacturers Association (WIMA). All ballpoint pens and many mechanical pencils sold throughout the world contain a small amount of metal lead, which is essential in order to create high-quality components, including pen points and limited components for mechanical pencils. Studies and supporting documents, which have previously been submitted to the United States Consumer Product Safety Commission (CPSC), were provided to MCPA. These documents directly address the absence of risk of lead exposure due to contact by children with ballpoint pens. As the documents show, ballpoint pens, which contain lead totals exceeding the limits prescribed in the Statute, will have no measurable adverse effect on public health or safety.

The estimated annual loading rate of lead from 50 million pens to the Littlefork River is 0.0055 µg/L which is approximately 900x lower than the state-specific water quality standard (5.1 µg/L) protective of chronic effects to freshwater aquatic life, as well as recreational water uses such as swimming, fishing, hunting, and boating. Based on the available data and the assumptions used in the assessment, the use and disposal of 50 million pens containing lead is not considered to pose a potential risk to freshwater aquatic life or recreational water use in the state of Minnesota. This assessment is considered to be conservative given that it is highly unlikely the exposure of lead from all pens used in the state of Minnesota will occur within a single body of water.

Conclusions

Minn. Stat. § 325E.3892 states that a person or business cannot "import, manufacture, sell, hold for sale, distribute or offer for use" in the state of Minnesota any product containing lead at more than 0.0009 percent by total weight (90 ppm) or cadmium at more than 0.00075 percent by total weight (75 ppm). The available data clearly demonstrates that most pigments contain cadmium in an encapsulated form which greatly reduces its bioavailability. As such, an analytical procedure capable of measuring the quantity of bioavailable cadmium in these products should be considered as an alternative to the total cadmium analysis required by the Statute. Furthermore, available studies, which were submitted to the MPCA, have shown that the presence of lead in pen tips and mechanical pencils have no measurable adverse effect on public health or safety.

INTRINSIK CORP.

Elliot Sigal, B.Sc. (Hon.), QPRA, UKRT, ERT
Vice President/Senior Toxicologist

References

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Swedish Chemicals Agency (KEMI). 2013. Annex XV Restriction Report: Proposal for a Restriction – Cadmium and Its Compounds in Artists' Paints.

Turner, A. (2018). Cadmium pigments in consumer products and their health risks. Science of The Total Environment. doi:10.1016/j.scitotenv.2018.12.096

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March 24, 2025

Rep. Josh Heintzeman
Committee Co-Chair
Environment and Natural Resources Finance and Policy Committee

Rep. Peter Fischer
Committee Co-Chair
Environment and Natural Resources Finance and Policy Committee

Position Statement on the Use of Lead in Writing Instruments

We, as a manufacturer of high-quality writing instruments, respectfully submit this statement in response to the recent legislative developments regarding the restriction of lead content in consumer products, including ink pens and mechanical pencils.

While we fully support the intent of such regulations to protect public health and safety, we believe it is essential to base such decisions on a clear understanding of product usage, scientific data, and actual risk of exposure.

In the case of mechanical pencils and certain pen tips, lead-containing brass is currently used in some internal components due to its unique machinability, durability, and stability. These parts are located **entirely inside the product** and are **never in direct contact with the user** under normal conditions of use. The risk of lead exposure from these components is, therefore, **negligible to non-existent**.

At present, there is **no widely available substitute material** that matches the performance, precision, and cost-efficiency of these lead-containing alloys for these specific applications. Forcing a material change without a suitable alternative would disrupt manufacturing, reduce product quality, and potentially eliminate access to affordable mechanical pencils and pens in certain markets.

We believe that a **risk-based approach to regulation**—focused on actual consumer exposure rather than theoretical material content—is the most scientifically sound and practical method to ensure safety without impeding innovation or access to essential everyday tools.

We sincerely urge legislators to consider the unique characteristics of writing instruments and support a targeted exemption for components that **pose no risk to human health** during normal use.

We remain committed to safety, transparency, and technological advancement, and will continue to explore lead-free alternatives as they become feasible.

Sincerely,

KOTOBUKI Co., Ltd.
HIROSHI YOKOISHI
Chief Executive Officer

March 25, 2025

Minnesota House of Representatives
Attn: Chair Josh Heintzman and Co—Chair Peter Fischer
Room G—3 Capitol Building
75 Rev. Dr. Martin Luther King, Jr. Blvd.
Saint Paul, MN 55155

Subject: Support for HF 737 – Exclusion of Keys and Key Fobs from Lead and Cadmium Prohibition

Dear Chair Heintzman and Co—Chair Fischer,

I am writing on behalf of the National Marine Manufacturers Association (NMMA), the Marine Retailers of the Americas Association (MRAA), and the Watersports Industry Association (WSIA) to express our support for HF 737 as amended, which excludes manufacturers from the provisions of Minnesota Stat. § 325E.3892 that prohibit certain lead and cadmium levels in keys and key fobs. NMMA is the leading trade association for the U.S. recreational boating industry, representing over 1,300 businesses, including manufacturers of recreational boats, marine engines, and accessories. Many of our members are small, family-owned businesses based in the U.S. Collectively, they account for more than 85% of the marine products sold in the U.S. The recreational boating industry contributes $230 billion to the national economy and supports over 812,000 jobs across 36,000 businesses nationwide.

WSIA serves as the primary advocate for the towed watersports industry, striving to strengthen and grow boating while protecting the interests of its member companies and recreational boaters. WSIA works to develop best practices, preserve waterway access, educate participants, and promote safety, particularly in towed watersports activities. With over 440 member companies, WSIA represents a diverse range of stakeholders, including manufacturers of boats, marine engines, accessories, and marine dealers.

MRAA is the leading trade association for North American small businesses involved in selling and servicing new and used recreational boats, as well as operating marinas, boatyards, and accessory stores. MRAA represents more than 1,300 retail locations and advocates for their interests.

The marine sector faces significant challenges under the current restrictions on lead and cadmium in marine keys and key fobs. These components are essential for the operation, security, and safety of boats, watercraft, and related machinery. Without a sufficient phase-out period or exemption for the marine industry, manufacturers would experience major disruptions, including costly retooling, sourcing alternative materials, and production delays. Alternatives to lead-containing materials, such as titanium or harder metals, are not only prohibitively expensive but could also damage key-cutting machines and accelerate wear on locking mechanisms, compromising the safety and durability of marine equipment.

The transition to non-lead and non-cadmium materials in the marine industry requires extensive testing to meet the high performance, durability, and corrosion resistance standards necessary for marine applications. Unlike other sectors, marine manufacturers work with highly specialized products that demand thorough development of alternatives. This process can take months or even years to implement

successfully. Without clear exemptions or phase-in provisions, this transition would be significantly hindered, leading to safety and operational challenges.

Exempting keys and key fobs from the lead and cadmium restrictions will enable our members to continue delivering high-quality, durable products to consumers, while maintaining the safety and performance standards the industry is known for. This exemption will also help avoid unnecessary financial strain and operational disruptions that could harm both manufacturers and consumers. We respectfully request the Committee's support for the revised version of H.F. 737.

Thank you for your time and consideration. We look forward to working with you and the broader Minnesota Legislature to find a solution that benefits both the public interest and the economic health of our industry. For any questions, please contact Jmcardell@nmma.org.

Sincerely,

Jesse McArdell

Senior Manager of Midwest
Government Relations
National Marine
Manufacturers Association

Lee Gatts

Vice President of
Government Affairs
Water Sports Industry

Chad Tokowicz

Government Relations
Manager
Marine Retailers Association
of the Americas

Wet Paint Testimony

Wet Paint has been selling artists' materials on Grand Avenue in St Paul for nearly 50 years. Darin and I have been involved for about 35 of those. We have 19 employees and in addition to the store on Grand we sell online to the rest of the nation and internationally. We have close relationships with the art and art education community and with the manufacturers and distributors in the art supply industry.

Cadmium pigments, mainly found in oil, acrylic and some watercolor paints, produce standard colors on the artist's palette. The color names on the paint tubes are things like Cadmium Yellow and Cadmium Red Deep. Artists look for "Cadmium" on the label and pay a premium for it. It's not used in cheaper paints or as a filler due to the extraordinary cost of the refined pigment. A 37ml tube runs between 25 and 75 bucks. Our manufacturers are small factories in places like Portland, Oregon, Upstate New York, Amsterdam, Dusseldorf, and Osaka who take extraordinary care in making it; for their own safety and because this quality of cadmium pigment is expensive and can't be wasted.

There's not a replacement for the performance of cadmium pigments in artists' paint. Artists' color is priced based on pigment availability and the art supply industry does not make their own, they buy from the same place as other industries.... so while it used to be common to use cadmium in industrial plastics, car paint, jewelry, etc that's no longer the case. A tube of cadmium red paint is 3-7 times more expensive than other colors on our shelf. There are paints called "Cadmium Hue" which are cheaper alternatives made by mixing other pigments to try and get the tone and color mixing properties close to the real thing. Squirted out of the tube the Hues can be a close match but when mixed with other colors on the palette they immediately fail to soften and cover the same way. They are either not as opaque as true cadmium, not as warm as true cadmium, or both. This is why real cadmium outsells the replacements, significantly, despite the cost.

Minnesota is the only place to have banned the sale of Cadmium in artist' paints, including California, including the EU. So our customers that want cadmium colors are ordering online wherever they can get it and some are driving to Michaels in Hudson, about fifteen minutes away. In an Instagram post about this situation, one professional who regularly shops with us, showed his haul - in addition to the Cadmium tubes, he went ahead and picked up all the other colors he needed at the same time. That's a four hundred dollar sale that should have been in St Paul, and - unless we plan to stop cars at the border – these sales will continue to be taken away from the few art shops left in the state. Wet Paint is currently no longer in the national marketplace when it comes to premium art supplies. Blick is, their warehouse is in Illinois. St Louis Art Supply is. Amazon is. Everyone is...unless you have your business in Minnesota.

Thank you for considering an exemption to the ban for this specialized use. It will serve the art community of Minnesota and allow our business to remain competitive.

[redacted] • Follow

[redacted] Goya made it to spring training! Always good to have the ole boy in the dugout for painting season. Had to get my cadmiums out of state, since Minnesota banned the sale of them, along with too-tight boxers, starting Jan. 1st. Way to go, sota

2w

30 likes

March 6

Add a comment... Post

SHDA
Security Hardware Distributors Association

March 24, 2025

Representative Josh Heintzeman
House Environment Chair
2nd Floor, Centennial Office Building
St. Paul, MN 55155

Re: In Support of HF737 - Removing Keys from Minnesota's Lead/Cadmium Prohibition

Thank you for the opportunity to submit this letter in support of HF737 removing keys from Minnesota's lead/cadmium prohibition. We feel it's important to convey the significant burden and expense that Minnesota businesses, homeowners, governmental authorities (including police and fire departments), and the agricultural community will bear without modifications to the lead/cadmium prohibition on keys passed in 2023.

Minnesota's law as currently written, in effect, bans every blade style key and key fob in the state Further, if enforced as written *Minn. Stat. §325E.3892* effectively prohibits the sale and/or use of keys for the following applications:

- Houses, offices, and businesses with keys to unlock or access the property;
- New or used cars, boats, motorcycles, ATVs, UTVs, golf carts, agricultural machinery, or other motorized vehicles utilizing a key or key fob;
- Office furniture with locking drawers;
- Locking toolboxes, truck toolboxes, or work trucks with keys
- Safes utilizing keys;
- Industrial equipment with safety equipment utilizing locks and keys;
- Refrigerators or freezers utilizing locks and keys;
- Padlocks; and
- Replacement blade style keys for key fobs any of the above.

Minn. Stat. §325E.3892 goes even farther than prohibiting the sale of keys and key fobs in the state it prohibits "offer for use" of keys and key fobs, which would prohibit a business or governmental agency from offering keys to operate business or governmental vehicles. This would severely inhibit the operation of police vehicles, fire vehicles, emergency medical vehicles, construction equipment, heavy duty trucks that transport goods, critical infrastructure equipment and facilities, and would also prohibit the use of keys to open office buildings and doors and other governmental facilities.

Except for California, no other state limits the lead or cadmium content in keys or key fobs. The Minnesota ban is significantly more stringent than the settlement reached in California after a referendum attempting to enact a ban was passed in 2001 (California is at 1.5% lead compared to Minnesota's 0.009%). And unlike other chemical bans enacted in Minnesota in recent

memory that have provided businesses time to identify and implement alternatives, the lead and cadmium prohibition went into effect also immediately, going into effect on July 1, 2023.

As background most metal keys are made of purchased and smelted brass, which contains lead at levels between .9% and 1.5%. Brass is a metal of choice for key manufacturing because of its balance between strength in-use and its ability to be machine cut; the lead in brass facilitates machinability. Brass is also not easily corroded. There are no reasonable alternatives available in sufficient volumes at reasonable cost. Potential alternatives, like titanium, are extremely expensive and will require all milling equipment to be reengineered since current machines cannot cut these harder keys. Alternatives will also wear lock pins and ignitions faster as they were not engineered to handle the harder materials. Alternative metals also increase the chance of keys suddenly breaking off in locks; brass has the tendency to deform/bend prior to sudden breakage preventing the total destruction of the locking mechanism.

We have reviewed the legislative history surrounding the enactment of *Minn. Stat. §325E.3892* noting that the lead and cadmium ban was not a stand-alone bill and legislators heard little testimony delineating the benefits of banning literally every blade style key and key fob in the state or the negative impacts to Minnesota businesses of doing so. The language first appeared in House and Senate omnibus budget bills as part of an effort to reduce lead and cadmium in children's toys and other products. We would note that when the MPCA testified on its initiative to reduce lead and cadmium in children's products as part of its budget overviews, no mention was made of why keys or key fobs were included in the list of prohibited products, and keys and key fobs are the only products on the list not intended to be used by young children, or as a personal self-care product.

We hope that over the coming weeks stakeholders can work with the MPCA and the Minnesota Legislature to improve the law so the state can continue to meet the goal of protecting children's health while lessening the burden on Minnesota businesses and consumers of banning all keys and key fobs in the state. Thank you for your consideration and we look forward to additional dialogue on how best to accomplish this.

Very Truly Yours,

Rob Justen
President, Doyle Security Products
Minneapolis, MN
Immediate Past President, Security Hardware Distributors Association

cc. Members of the House Commerce Finance Policy Committee

Via Email

March 24, 2025 ***Reply to St. Paul***

Rep. Josh Heintzeman
Committee Co-Chair
Environment and Natural Resources Finance and Policy Committee
Centennial Office Building
658 Cedar Street
2nd Floor
Saint Paul, MN 55155
rep.josh.heintzeman@house.mn.gov

Rep. Peter Fischer
Committee Co-Chair
Environment and Natural Resources Finance and Policy Committee
Centennial Office Building
658 Cedar Street
5th Floor
Saint Paul, MN 55155
rep.peter.fischer@house.mn.gov

Re: The Writing Instrument Manufacturers Association's Letter to the House Environment and Natural Resources Finance and Policy Committee in Support of Minnesota House Bill HF737, Amending Minn. Stat. 325E.3892, Lead and Cadmium in Consumer Products; Prohibition.

Dear Rep. Heintzeman and Rep. Fischer:

The Writing Instrument Manufacturers Association (WIMA) has significant concerns with the lead restrictions imposed by Minn. Stat. 325E.3892 (the Statute). Specifically, the Statute would ban the sale of most pens and mechanical pencils to Minnesota Citizens. Approximately 50 million pens and mechanical pencils are sold in Minnesota each year. During the last session, the Legislature approved a moratorium on enforcement of the Statute for pens and mechanical pencils until July 1, 2025. However, once the moratorium expires, the ban will be in effect. Minnesotans should not be singled out as the only citizens in the United States prohibited from purchasing nearly all of the currently available pens and mechanical pencils. This ban will affect most pen and mechanical pencil manufacturers. WIMA urges an exemption of these products from the reach of the Statute.

As background, manufacturing high-quality pens and mechanical pencils requires the addition of small amounts of metal lead embedded in the matrix of the tip of the writing instrument, which has a very small surface area. This technology, design and methods have been refined through decades of research and development and importantly, by

investing significant amounts of capital and time. Notably, the manufacture of pens and mechanical pencils requires the refinement of machines and a manufacturing process that is suitable for mass production while assuring the high quality and functionality of the products. Compliance with the restrictions provided by the Statute is neither technologically nor economically feasible because there is a lack of availability of lead-free alternative materials to permit large-scale mass production necessary to meet public demand at an affordable price. While some manufacturers, such as Mikron, have shared their perspective regarding feasibility, these manufacturers do not have the full visibility of the impact that such material change has on the whole production chain and have shared that there are challenges to changing to lead-free alternatives. Notably, the loss of machinability affects not only tool wear, but also the dimensional stability of the points and their compliance with the geometrical tolerances needed to assemble them on refills.

While the Statute seeks to protect consumers, with a focus on exposure to children, from the potential effects of lead exposure, the Statute's broad and overreaching language imposes restrictions on products which do not pose a quantifiable threat to public health. As part of WIMA's effort to secure an exemption from the Statute last legislative session, WIMA submitted several studies to the Minnesota Pollution Control Agency (MPCA) that consistently demonstrate that exposure to lead-containing components in pens and mechanical pencils does not pose a health risk to consumers. Copies of these studies have been included with this letter for reference. Crucially, these studies address the underlying concern the Statute seeks to protect against – lead exposure to children. Scientific evidence shows that school aged children do not put pen tips in their mouths, and in the limited instances when indirect ingestion occurs, the exposure is negligible and does not pose a health risk to children. Moreover, pens and mechanical pencils are general use products and are not considered children's products. The United States Product Safety Commission (CPSC) confirmed in a June 4, 2009 letter to WIMA that pens were not children's products subject to the lead restrictions of section 101(a) of the Consumer Product Safety Improvement Act (CPSIA).

As a collateral issue, the MPCA has raised concerns regarding the potential environmental impact of lead from pens and mechanical pencils. To alleviate these concerns, WIMA retained experts to conduct an environmental assessment to evaluate the potential environmental impact of lead from pens and mechanical pencils. The results of this assessment showed an insignificant impact. Please see attached assessment completed by Elliot Sigal, Vice President and Senior Toxicologist at Intrinsik Corp.

The Statute does not attempt to limit the scope of the prohibition to products which may cause harm. Instead, it focuses on the material content of the products and their components and presumes and unsubstantiated threat of exposure. In fact, there are no medical studies that support the conclusion that ballpoint pens and mechanical pencils pose a threat of lead poisoning. Because the lead content is present in the small tip of pens and mechanical pencils, exposure to the pen point is limited due to the small surface area. Lead that is present in the exposed portion of the pen point is embedded in the matrix of the metal allow and is not a coating that can be removed. Therefore, exposure

to the lead from these writing instruments is extremely limited and poses no measurable health risk.

Failure to provide an exemption for these writing instruments will result in the prohibition of the sale and possession of most pens and mechanical pencils, which are widely used and are necessary to business, commerce and education in Minnesota. Such a result is arbitrary and unfair to the industry and to all Minnesota consumers who rely on the availability of pens and mechanical pencils in their day-to-day lives. The sweeping ban cannot reasonably be the intent of the Legislature in adopting the Statute.

Therefore, given the pervasive effects of the Statute, the available scientific evidence showing no significant health hazards resulting from exposure to lead from writing instruments, and the lack of feasible alternative materials, the only reasonable solution is to exempt pens and mechanical pencils from the reach of the Statute.

For all the reasons stated above, we kindly request that the House Commerce Finance and Policy Committee support and adopt House Bill HF737 to amend Minn. Stat. 325E.3892 to exclude pens and mechanical pencils from the Statute.

Thank you for your time and attention.

/s/ *William L. Moran*

William L. Moran
Attorney at Law
Haws-KM, P.A.

Enclosures

ATTACHMENT 1

Attachment 2

CONSUMER PRODUCTS SERVICES DIVISION

BUREAU VERITAS

BIC USA, INC. (CT)

Technical Report:	**(5113)030-0017 Revision**	March 8, 2013
Date Received:	January 30, 2013	Page 1 of 3

JOANNE CARSON
BIC USA, INC. (CT)
ONE BIC WAY, SUITE 1
SHELTON, CT 06484
UNITED STATES

Sample Description:	BIC BEGINNER PEN ISR #3828		
Vendor:	N/A	Sample Size:	7
Manufacturer:	N/A	Style No(s):	N/A
Buyer:	N/A	SKN/SKU No.:	N/A
Labeled Age Grade:	N/A	PO No.:	N/A
Appropriate Age Grade:	N/A	Ref #:	N/A
Client Specified Age Grade:	N/A	Country of Origin:	NO INFORMATION
Tested Age Grade:	N/A	Assortment No.:	N/A
UPC Code:	N/A		

EXECUTIVE SUMMARY:

The sample(s) was tested to the following requirement(s) and the data provided is for informational purposes only

- The total lead content of 100ppm requirements in substrate materials (Consumer Products Safety Improvement Act (CPSIA) of 2008).

Note: **At the request of the client, this report has been revised to add sample preparation statement.**

BVCPS Buffalo Contact Information for this Report:

Administrative Questions:	Kathy Kubiak	Phone: 716-505-3465	kathy.kubiak@us.bureauveritas.com
Technical Questions:	Alison Tuzzolino	Phone: 716-505-3434	alison.tuzzolino@us.bureauveritas.com

Bureau Veritas
Consumer Products Services, Inc

Alison Tuzzolino

Alison Tuzzolino, Product Chemist
Analytical Services

/sw

cc: GILLIAN ROSENBLOOM, BIC USA, INC. (CT)

[illegible]

RESULTS:

TOTAL LEAD CONTENT IN SUBSTRATE (100PPM) (Consumer Product Safety Improvement Act (CPSIA) of 2008)

Test Method: U.S. CPSC-CH-E1001-08.1 (June 21, 2010) or U.S. CPSC-CH-E1002-08.1 (June 21, 2010)

Sample Preparation: Sample was prepared by cutting the accessible exposed metal tip of the pen.

Analyte				Lead	
Requirement: Maximum allowable limit.				100 mg/kg	
Sample Description				Result (mg/kg)	Conclusion
	Color / Component	Location	Style		
(A)	Metal	Pen tip		8720	Data

LT = Less Than *mg/kg = milligrams per kilogram (ppm = parts per million)*
* = *Average of duplicate analyses*

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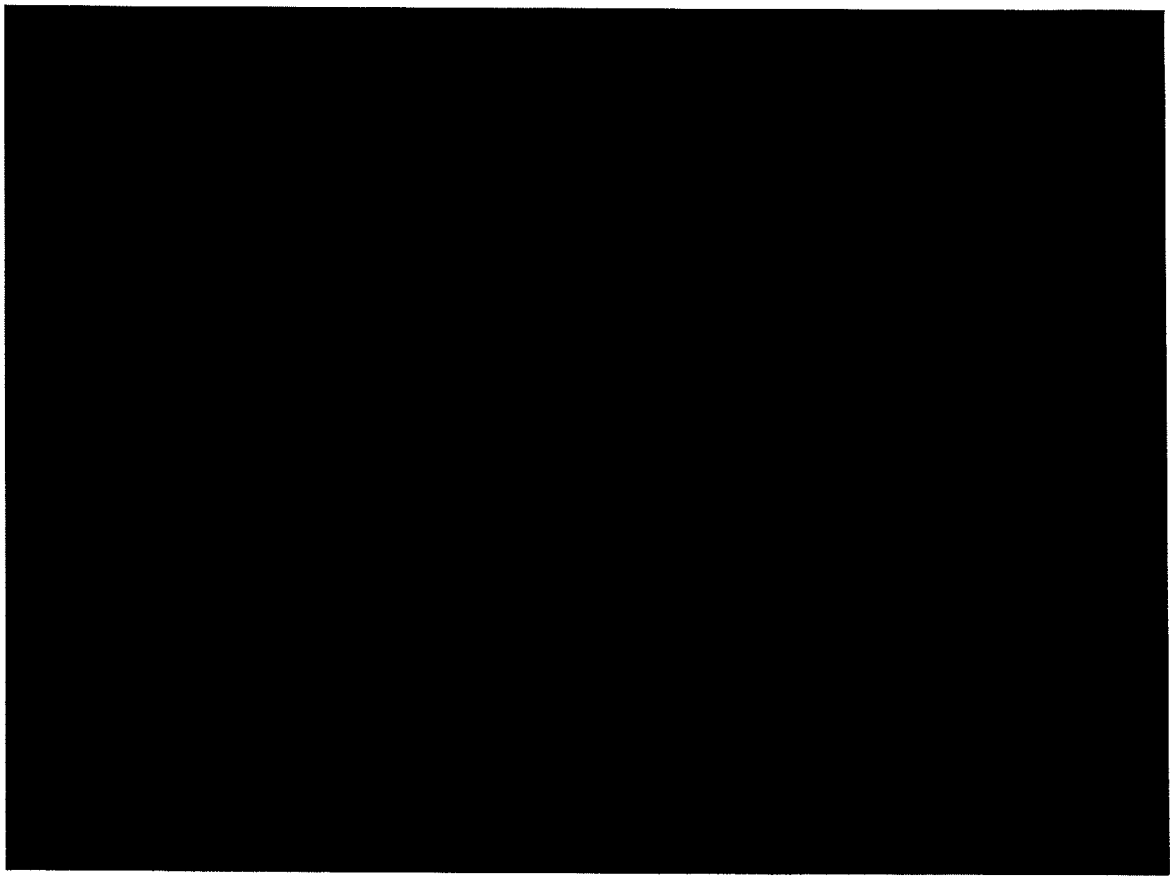
EXHIBIT #1



SAMPLE PRODUCT

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ATTACHMENT 2

CONSUMER PRODUCTS SERVICES DIVISION

BUREAU VERITAS

BIC CORPORATION

Technical Report: **(5113)030-0019** February 06, 2013
Date Received: February 01, 2013 Page 1 of 3

JOANNE CARSON
BIC CORPORATION
ONE BIC WAY, SUITE 1
SHELTON, CT 06484
UNITED STATES

Sample Description:	BIC BEGINNER PEN ISR #3828		
Vendor:	N/A	Sample Size:	7
Manufacturer:	N/A	Style No(s):	N/A
Buyer:	N/A	SKN/SKU No.:	N/A
Labeled Age Grade:	NOT PRESENT	PO No.:	N/A
Appropriate Age Grade:	NOT REQUESTED	Ref #:	N/A
Client Specified Age Grade:	4+	Country of Origin:	NO INFORMATION
Tested Age Grade:	CHILDREN PRODUCTS, OVER 4 YEARS OF AGE	Assortment No.:	N/A
UPC Code:	N/A		

EXECUTIVE SUMMARY:

The sample(s) MEETS the following requirement(s)

The mechanical hazards requirements of the tested sections of Canada Consumer Product Safety Act, Toys Regulations, SOR/2011-17 and Schedule 2.

The sample(s) was tested to the following requirement(s) and the data provided is for informational purposes only:

- The mechanical hazards requirements of 16 CFR 1500, "Federal Hazardous Substances Act Regulations"
  - No sharp points or sharp edges were present when tested according to the specified regulations and age grade
  - No small parts were released when tested according to the specified regulations and age grade

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website www.bureauveritas.com/cps

[illegible]

BVCPS Buffalo Contact Information for this Report:

Administrative Questions:	Kathy Kubiak	Phone: 716-505-3465
Technical Questions:	Philip Carlisle	Phone: 716-505-3399

Bureau Veritas
Consumer Products Services Inc

Philip Carlisle
Product Test Engineer,
Toy and Juvenile Products Department

/gf

cc: GILLIAN ROSENBLOOM, BIC CORPORATION

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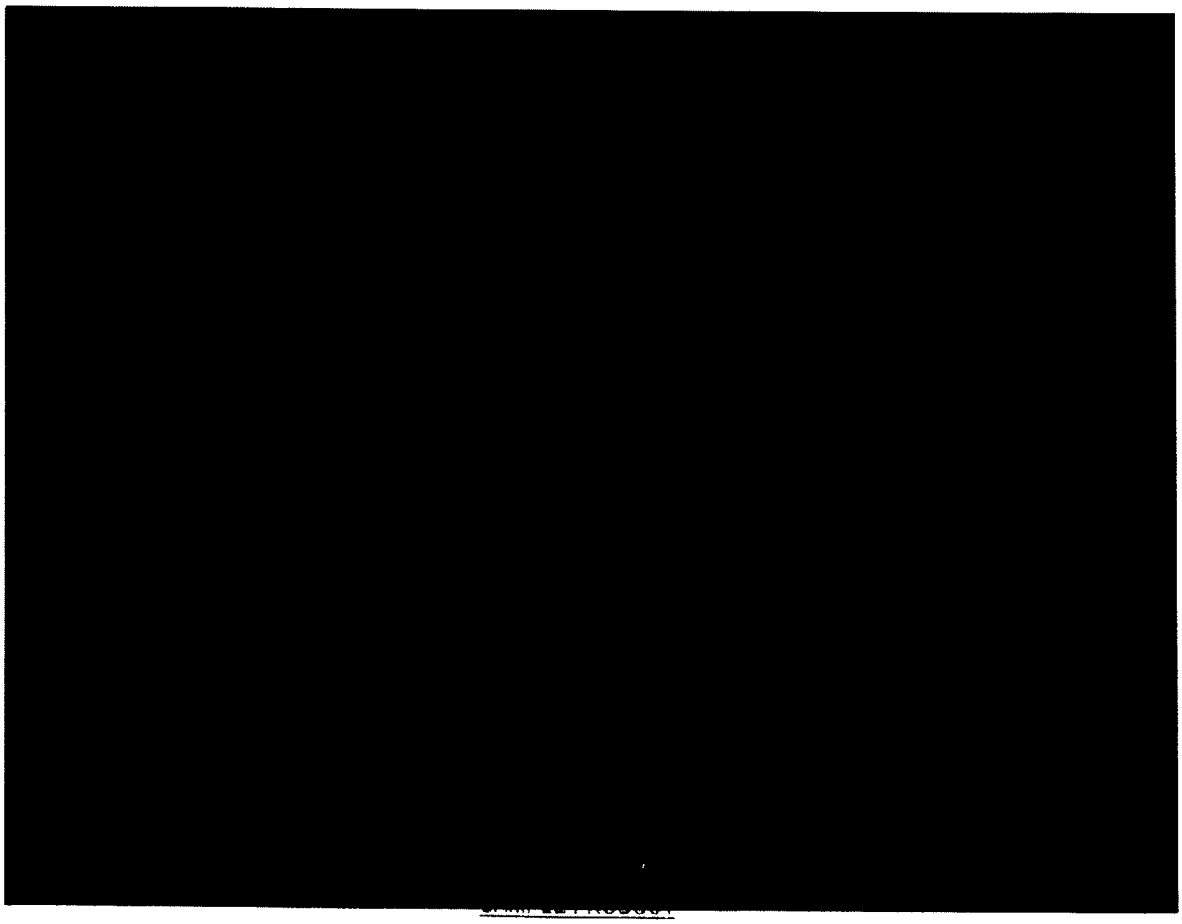
EXHIBIT # 1



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ATTACHMENT 3

Exponent
Failure Analysis Associates®

March 20, 2013

Statement of Christine T. Wood, Ph. D.

I have been asked by BIC to evaluate the likelihood of young children ingesting or mouthing the point of BIC Children's Pens.

I received a Bachelor's Degree in psychology with Distinction and Honors from Stanford University and hold a Ph.D. in experimental psychology also from Stanford University.

I am a Principal Scientist and the Director of the Human Factors Practice at Exponent. My work with Exponent includes the analysis and evaluation of human factors issues for many different products. As part of that work, I analyze the developmental abilities and limitations of children at different ages and the ways these impact how they engage in activities and use products in different environments. I investigate the accident patterns that are unique to children and the effectiveness of strategies used to reduce child injury. I have conducted tests of young children to investigate their patterns of interactions with various products, including toys, play yards, high chairs, child restraint systems, controls inside motor vehicles, and trunks of motor vehicles.

Based on my review of the materials cited in this statement, examination of an exemplar BIC Children's Pen, my experience, education, and training, I offer the following opinions to a reasonable degree of scientific certainty:

Ingestion of the point is unlikely.

The point, which is the subject of this functional purpose exception request, is not likely to be ingested. BIC conducted use and abuse testing of the BIC Children's Pen pursuant to ASTM F926-11 for products intended for use by children who are at least three years of age but less than six years of age.[1] The results of that testing confirmed that the point and point support do not detach from the writing instrument after use and abuse testing. Further, unlike other pen designs, the BIC Children's Pen is designed without a cap, clip, or pen body that can be opened, preventing access to the spring, other interior components, and potentially the tip.

[1] BIC Beginner Pen, Technical Evaluation (5113) 030-0019, Bureau Veritas, February 06, 2013

Mouthing of the point is unlikely.

The point is not likely to be placed in the mouth. The frequency of object-to-mouth contacts has been observed for children of different age groups. Children within the approximate age range of users of BIC Children's Pens (i.e. 5 to 12 years old) have the lowest frequency of object-to-mouth contacts compared with children in younger age groups.[2] For example, in a summary of the published scientific literature on mouthing prepared by the U.S. Environmental Protection Agency, for the age group 6 years through 10 years, on average, there was a frequency of approximately one object-to-mouth contact observed per hour indoors.[3] In contrast, the frequency of object-to-mouth contacts per hour for younger children was at least ten times higher. Studies of mouthing behavior of children in the relevant age group report a wide variety of objects being mouthed including fingers/hands, clothing, blankets, toys, and paper/wrappers.[4] Pencils have sometimes been identified. In the literature reviewed by the EPA,[5] I am unaware of any published study of mouthing for the relevant age group in which it was reported that pens were mouthed. Further, the point of a pen is unlikely to be mouthed because the orientation of a pen when held in the hand to write does not present the point toward the user. The design features of the BIC Children's Pen that make ingestion of the point unlikely also contribute to making mouthing the point unlikely. The point is retractable, and when retracted the point is not available for contact with the mouth.

The points of many traditional ballpoint pens generally available in the market today are composed of the same metal alloys as the point of the BIC Children's Pen, as more fully described in BIC's submission to the CPSC to which this statement is attached. Mouthing and ingestion of the points of pens, in general, is unlikely. The introduction of BIC Children's Pens into the marketplace will not increase the likelihood of mouthing and ingestion of points compared to children's use of traditional ballpoint pens. Unlike other styles of pens that have a

---

[2] Xue, J; Zartarian, V; Tulve, N; Moya, J; Freeman, N; Auyeung, W; Beamer, P. (2010). A metaanalysis of children's object-to-mouth frequency data for estimating non-dietary ingestion exposure. J Expo Sci Environ Epidemiol 20: 536-545. http://dx.doi.org/10.1038/jes.2009.42.

[3] U.S. Environmental Protection Agency (EPA). (2011) Exposure Factors Handbook: 2011 Edition. National Center for Environmental Assessment, Washington, DC; EPA/600/R-09/052F. Available from the National Technical Information Service, Springfield, VA, and online at http://www.epa.gov/ncea/efh., Chapter 4, Table 4-1.

[4] Beamer, P; Key, ME; Ferguson, AC; Canales, RA; Auyeung, W; Leckie, JO. (2008). Quantified activity pattern data from 6 to 27-month-old farmworker children for use in exposure assessment. Environ Res 108: 239-246. http://dx.doi.org/10.1016/j.envres.2008.07.0 07: Stanek, EJ, III; Calabrese, EJ; Mundt, K; Pekow, P; Yeatts, KB. (1998). Prevalence of soil mouthing/ingestion among healthy children aged 1 to 6. Journal of Soil Contamination 7: 227-242.

[5] U.S. Environmental Protection Agency (EPA). (2011) Exposure Factors Handbook: 2011 Edition. National Center for Environmental Assessment, Washington, DC; EPA/600/R-09/052F. Available from the National Technical Information Service, Springfield, VA, and online at http://www.epa.gov/ncea/efh.

fixed, extended point, the point of the BIC Children's Pen completely retracts by twisting one half of the pen body. In addition, the BIC Children's Pen is designed to meet the needs of children who are learning proper gripping techniques and control of a pen while writing.

Sincerely,

Christine Wood

Christine T. Wood, Ph.D.
Principal Scientist
Director, Human Factors
(650) 688-7134 direct
(650) 328-2981 fax
cwood @exponent.com

ATTACHMENT 4

Attachment 6

Technology Sciences Group Inc.
712 Fifth St., Suite A
Davis, CA 95616
Direct: (530) 757-1281
Fax: (530) 757-1299
E-Mail: GGorder@TSGUSA.com

Greg W Gorder, Ph.D.
Senior Managing Scientist

STATEMENT OF GREG W. GORDER Ph.D.
March 21, 2013

My name is Greg W. Gorder and I am a Senior Managing Scientist at Technology Sciences Group Inc. (TSG). I am an experienced exposure/risk assessor and obtained a Ph.D. in Entomology/Environmental Toxicology at Iowa State University. I joined TSG in 2000. My C.V. is attached to this Statement.

On behalf of BIC USA Inc. (BIC), I was asked to assess potential exposures to lead from the BIC Children's Pen to determine if it meets the standard of "no measureable increase in blood lead levels of a child" as required for an exception under the Consumer Product Safety Improvement Act (CPSIA). The Children's Pen requires an exception because it has a nickel-silver point that is partially accessible and exceeds the 100 ppm total lead standard for children's products under the CPSIA. TSG developed a test protocol to assess lead exposures that could potentially occur as a result of extensive, purposeful dermal contact with the pen point followed by hand-to-mouth contact, even though contact of this type is very unlikely to occur. The attached protocol (**Exhibit 1**) used a wipe test for lead based on the NIOSH 9100 wipe test and increased the contact per wipe to 30 strokes to match the approach the Consumer Product Safety Commission (CPSC) used in their vinyl wipe test. The BIC test evaluated lead released from both the accessible portion of the conical-shaped nickel-silver point (i.e., the wipe samples) and the ball at the tip of the point that contacts the writing surface (i.e., the ink controls). The test represented worst-case, infrequent exposures because dermal contact with the nickel-silver point is unlikely during normal use or abuse (e.g., abuse does not increase accessibility of the point).

Summary: Use of the BIC Children's Pen to apply ink marks to a wipe did not result in measurable lead release (lead reporting limit of 0.1 µg/wipe) as shown by the ink blank results (**Exhibit 2**[1]). Squeezing the accessible nickel-silver pen point between the thumb and index finger and wiping for 30 full 360 degree rotations resulted in an average lead release of 0.62 µg/wipe. Squeezing the accessible nickel-silver pen point between the thumb and index finger and wiping for 120 full 360 degree rotations resulted in an average lead release of 1.05 µg/wipe, showing that the rate of lead release decreases dramatically with increased contact (i.e., the 4-fold increase in wiping resulted in just a 1.7-fold increase in lead released). Lead release rates may be exaggerated in the first wipes of a new pen.

Conclusion: The 0.62 µg of lead average for 30-rotation wipes represents a worst-case estimate for transfer to a user's fingers that might occur on an infrequent basis due to extensive, purposeful dermal

[1] Bureau Veritas, March 6, 2013. BIC Children's Ball Pen Point Wipe Tested for Lead.

contact. This could lead to potential ingestion of 0.31 µg of lead based on a presumption of 50% hand to mouth transfer often used by CPSC staff. CPSC identified 2.2 µg/day of ingested lead as the exposure threshold for "no measurable increase in blood lead levels of a child"[2] based on average daily exposures. Potential daily ingestion of 0.31 µg of lead is below the CPSC threshold; however, extensive, purposeful lead exposures of the type measured for the pen point would occur infrequently, if at all because the test was designed to determine how much lead could be released rather than mimic potential exposures from product use. Even if we presume that average daily exposures to lead from the pen point are 0.31 µg/day, those exposures would be 7-fold below the CPSC threshold for no measurable increased in blood lead levels of a child.

Considerations and Assessment

Dermal Exposure to Lead from the BIC Children's Pen is Unlikely to Occur: Numerous factors make it unlikely that use of the pen will result in dermal exposure to lead at the level measured including the following:

- **Impossible to Grasp Nickel-Silver Point and Write:** When used for writing, there will be no dermal contact with the pen point because it is impossible to grasp the pen by the accessible nickel-silver point and still write with the pen.

- **Difficult to Contact Point While Writing:** As shown in the photo in Exhibit 2, the BIC Children's Pen has a ridge above the point to assist with the writing grasp. The ridge makes it unlikely that there will be dermal contact of any type with the point during normal use.

- **Lead Not Transferred with Ink Released from the Point:** The ink controls in Exhibit 2 show that when marking with the pen, lead is not released. If a child were to write on their skin, measurable levels of lead would not be transferred to the skin.

Test Method is a Very Conservative Estimate of Exposures on Days Exposures Occur: The 30 rotation test was based on the existing CPSC wipe test for lead in vinyl (i.e., 3 x 10 wipe strokes = 30 wipe strokes) rather than anticipated exposure from the BIC Children's Pen. 30 rotations of the pen is nearly a minute of squeezing and rotating so it far exceeds typical contact with the pen point.

- **Potential Dermal Exposures = 0.62 µg [Dermal]:** This is the average result for 30-rotation wipes in Exhibit 2. The 30-rotation test result shows that it is possible to transfer lead by squeezing the pen point and rotating; however, the test results represent a worst-case exposure scenario that would occur infrequently if at all.

---

[2] CPSC Staff Report, November 2012. CPSIA Section 101(b): Functional Purpose Exception from Lead Content Limit for Children's Products for a Specific Product, Class of Product, Material, or Component Part.

Exposure Assessment and Potential Adjustments: Exposure presumptions that should be considered for adjustment in the assessment include the frequency for exposures and the ongoing lead release levels.

- **Hand-To-Mouth Transfer Fraction = 0.5 [Ingestion Fraction]:** Lead transferred from the BIC Children's Pen to the user's skin would need to be ingested to affect blood lead level. Ingestion primarily applies to lead on a child's finger tips. Transfer occurs due to hand-to-mouth transfer and can be direct (e.g., placing fingers into their mouth) or indirect (e.g., handling food or an object and then placing the food or object into their mouth). CPSC often presumes that 50% of the lead on a child's fingertips can be ingested and that was the level identified in the November 2012 staff report cited in footnote 2.

- **Potential Adjustment, Exposure Frequency:** CPSC staff based the threshold level of 2.2 µg/day lead ingested on calculations using the US Environmental Protection Agency's Integrated Exposure Uptake Biokinetic (IEUBK) Model. The IEUBK model presumes that exposures occur daily so the 2.2 µg/day threshold is an average daily exposure. Exposures to lead at the level measured by 30 rotations would occur infrequently, if at all, because the 30 surface wipes (i.e., 30 rotations) followed the general approach used in the CPSC vinyl wipe test and did not mimic minimal contact with the pen point that could occur during product use.

- **Potential Adjustment, Lead Release Is Lower After Initial Rotations:** The 120-rotation wipes (i.e., over 3 minutes of squeezing and rotating) contained just 1.7-fold more lead than the 30 rotation wipes showing that removable lead levels decrease with increased contact and may only apply to newly manufactured points. Lead release over the final 90 rotations may be a better estimate of ongoing lead release than the initial 30 rotations. If so, the estimate would change to 0.14 µg per 30 rotations (i.e., 1.05 µg - 0.62 µg = 0.43 µg/90 rotations or 0.14 µg/30 rotations), over a 4-fold adjustment relative to the 30-rotation result.

Although the potential adjustments described above may be appropriate, they have not been applied. Exposures were calculated for the purpose of the CPSIA exception as shown below using Eq 1:

$$\textit{Exposure} = \textit{Dermal} \times \textit{Ingestion Fraction} \qquad \textit{(Eq. 1)}$$

$$= 0.62\ \mu g/day \times 0.5 = \textit{0.31 µg/day}$$

The assessed exposure of 0.31 µg/day is over 7-fold below the 2.2 µg/day threshold for "no measurable increase in blood lead levels of a child in the November 2012 CPSC staff report.

Respectfully submitted,

Greg W. Gorder

Exhibit 1

Pen Point Wipe Test Protocol

Technology Sciences Group Inc.
Greg W Gorder, Ph.D.
Senior Managing Scientist

TSG

WIPE PROTOCOL: Pen Tip-to-Hand Simulated Transfer Using Modified Method NIOSH 9100:

Method NIOSH 9100 is modified as follows to measure accessible lead that could potentially transfer from pen tip to hand. Cross out text represents deletions from NIOSH Method 8100 and underline text represents additions:

PURPOSE:	Determination of surface contamination by lead and its compounds.
LIMIT OF DETECTION:	Analysis will be conducted ~~2 µg Pb per sample (0.02 µg/cm 2 for 100 cm 2 area)~~ by flame AAS or ICP~~, 0.1 µg Pb per sample (0.001 µg/cm 2 for 100 cm 2 area) by~~ or graphite furnace AAS, as needed to obtain a detection limit no higher than 0.5 µg/wipe.
FIELD EQUIPMENT:	~~1. Bags, plastic, sealable (e.g., with attached wire, tape or "zip" type seal),~~ 2. Sample pads, ~~2" x 2", sterile cotton gauze (Curity™, Johnson & Johnson™, or equivalent), or~~ ashless quantitative filter paper. NOTE: Wash'n Dri™ wipes may also be used. Other wipes may not ash properly, or may have a significant lead blank value. 3. Gloves, latex, disposable. 4. ~~Template, plastic, 10 cm x 10 cm, or other standard size.~~Two BIC Beginner's Pens 5. Water, distilled, in plastic squeeze bottle.
SAMPLING:	1. Using a new pair of gloves, remove a ~~gauze~~ pad from its ~~protective~~ package. Moisten the ~~gauze~~ pad with approximately 1 to 2 mL of distilled water. NOTE 1: Apply no more distilled water than that necessary to moisten approximately the central 80% of the area of the gauze pad. Excess distilled water may cause sample loss due to dripping from the gauze pad. NOTE 2: If using the premoistened Wash'n Dri™, omit the distilled water. 2. ~~Place the template over the area to be sampled.~~ Wipe First BIC Beginner's Pen as Follows: Fold pad into quarters and grasp with left hand (reverse if left handed) holding between thumb and index finger. Extend pen tip to writing position. Grasp pen with right hand (reverse if left handed) and place pen tip between pad (i.e., pen tip surrounded on all sides by pad) with pen tip squeezed firmly between thumb and index finger. Rotate pen back and forth making quarter to half turns with right hand while firmly grasping pen tip within pad in left hand (hands reversed if left handed) wiping ~~Wipe~~ the pen-tip surface to be sampled with firm pressure for 15 seconds making at least 30 partial rotations of the pen (if necessary to make at least 30 rotations, extend the time)~~, using 3 to 4 vertical S-strokes. Fold the exposed side of the pad in and wipe the area with 3 to 4 horizontal S-strokes. Fold the pad once more and wipe the area with 3 to 4 vertical S-strokes.~~

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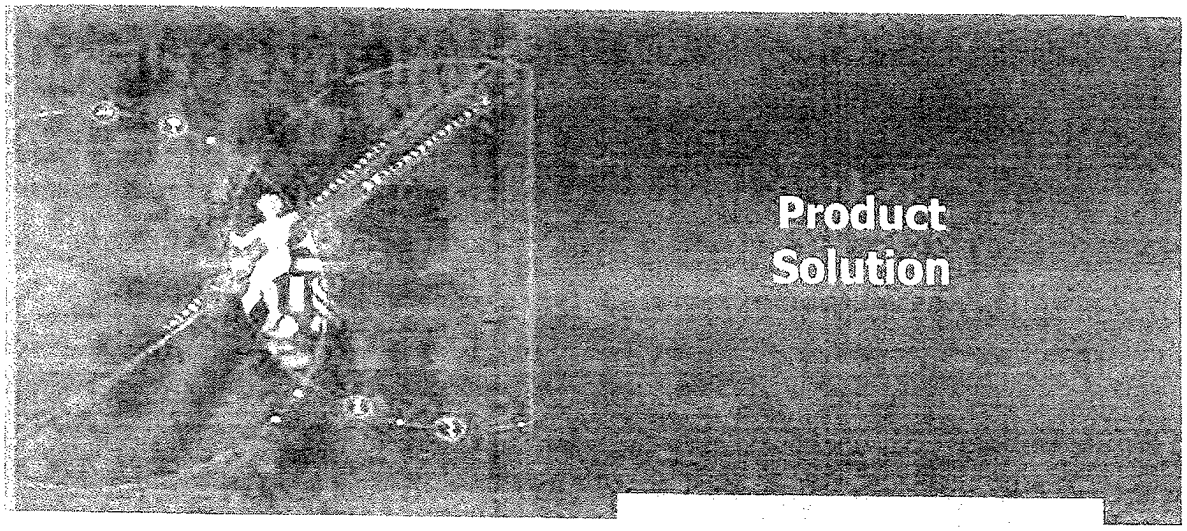
3. ~~Fold~~ Place the folded pad, ~~exposed side in, and place it~~ in a new plastic bag. Seal and label the bag clearly. Discard the gloves.
4. Wipe Second BIC Beginner's Pen as Follows: Repeat step 1 to moisten pad. Fold pad, extend pen tip, and grasp pen and pad as described in step 2. Rotate pen tip back and forth as described in step 2 but for at least 1 minute or 120 partial rotations. Repeat step 3 to label sample.
~~4. Clean the template in preparation for the next wipe sample.~~
5. Include two blank pads (moistened and placed in bags) with each sample set.

SAMPLE PREP: **Use the procedure of NIOSH Method 7105**, including final sample dilution to 10 mL
NOTE: Additional portions of nitric acid may be needed for complete digestion of the sample, including the pad. Include appropriate media and reagent blanks.

MEASUREMENT: Analyze ~~Screening of~~ all samples by flame AAS or ICP~~, followed by~~use or graphite furnace AAS ~~for those samples giving "Not Detected" is an efficient scheme~~to obtain a detection limit of 0.5 µg/per sample or less. Use the procedures of **NIOSH Methods** 7082 (Lead by flame AAS), 7300 (Elements by ICP), **7105** (Lead by graphite furnace AAS), **or other appropriate methods** such as ASTM E1613-12.

Exhibit 2

Bureau Veritas Report: Wipe Test Data



Product Description: **BIC Beginner Ball Pen Tip wipe tested for Lead**

Report Number:
(5113)036-0119 Revision 1

Received Date:
February 5, 2013

Report Date:
February 14, 2013

Revision Date:
March 6, 2013

Prepared for:

Ms. Gillian Rosenbloom
BIC Corporation
One BIC Way, Suite 1
Shelton, CT 06484

Contents:
Report: Pages 1-4

Bureau Veritas Consumer Product Services, Inc.
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Prepared by: Mike Monaco
Bureau Veritas
Consumer Product Services -
Engineering Services Group

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Project Scope

At the request of the client, (4) four samples of BIC Beginner Ball Pens were submitted for a Product Solution to analyze the amount of lead in the pen tips. The method for wiping the pen tips both 30 times and 120 times as well as the unit of measure, reporting limit required were all supplied by the client's toxicology firm. In addition, BVCPS was asked to perform and supply information on laboratory control sample wipes.
An e-mail quotation, #ESQ130122, was supplied by Bureau Veritas Consumer Products Services, Inc. (BVCPS) to the client outlining the price and scope of work to be performed to meet the client's request.

Executive Summary

Please refer to the results section of the report for the chart illustrating the data obtained from the testing conducted on the pen tips. Also please refer to the write-up and chart in the Methods/Evaluation section of the report for the laboratory control sample wipes.

Samples/Products Tested

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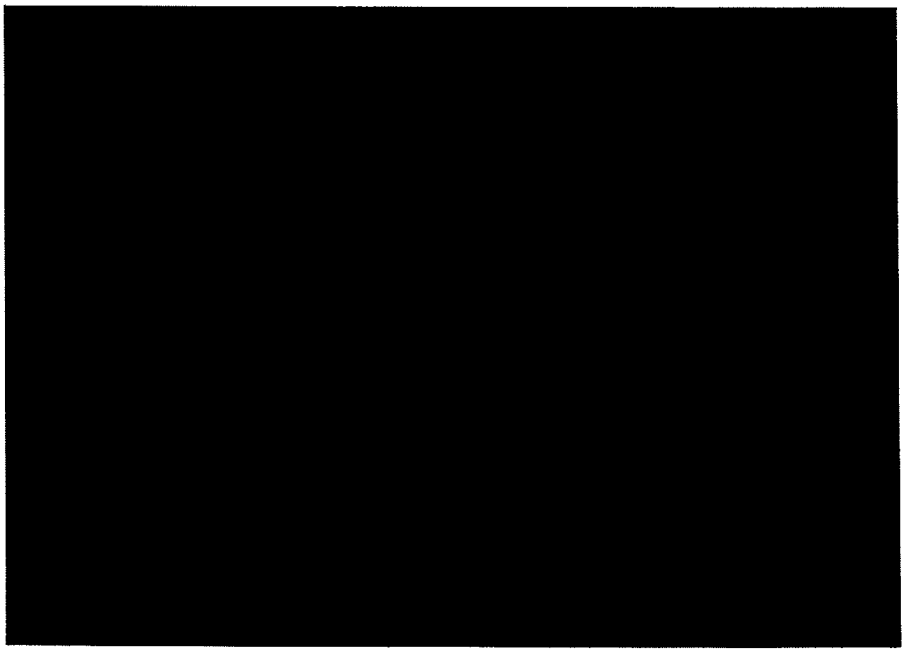


CONFIDENTIAL

Methods / Evaluation

This Product Solution utilized the following method which was directed by the client's toxicology firm:

Wipes were taken using Palintest wipe media in accordance with NIOSH Method 9100. The tips of two pens were wiped 30 times each and the tips of the other two pens were wiped 120 times each.

Wipe samples were collected by folding the Palintest wipe material into a triangular configuration. The tip of the pen was held inside the wipe, squeezed between the thumb and index finger, and rotated a full 360° a total of 15 times. The tip of the pen was then removed and placed into a clean area on the same wipe and rotated another 15 times. Therefore, the pens with 30 rotations were sampled on two areas of the wipe material. The pens with 120 rotations were sampled on eight clean areas of the wipe material. The 30 rotation wipes represented nearly one minute of wiping and 120 rotations represented at least three minutes of wiping. Ink was released from the pen tips during wiping.

The individual wipe samples were digested using nitric acid, sulfuric acid, and hydrogen peroxide according to OSHA method ID-125 (Metal and Metalloid Particulates in Workplace Atmospheres). The resulting extract was analyzed for lead using inductively coupled argon plasma with mass spectrometry (ICP-MS).

Quality control samples (two blank wipes, four laboratory control spikes, and ink controls) were prepared and analyzed along with the samples. The quality control spikes were created by adding a known amount of lead to a wipe, in duplicate, at levels 3X the reporting limit (0.3 µg) and 5X the reporting limit (0.5 µg).

As shown in the table below, the average recovery of the laboratory control spikes was 109%.

Laboratory Control Spike Level (µg/wipe)	Recovery (%)	
	Trial 1	Trial 2
0.3	107	109
0.5	109	111

In blank wipes there was no lead detected above the reporting limit of 0.1 microgram/wipe.

The presence of lead in the ink was evaluated by placing an ink mark on a Palintest wipe to mimic the collected samples, without rotating the pen tip against the wipe. The four ink-marked wipes were prepared and analyzed the same way as the pen tip rotation wipes. Ink controls did not have any lead detected above the reporting limit of 0.1 micrograms/wipe.

Results

The evaluation and analysis conducted on the pen tips of the four BIC Beginner Ball Pens products exhibited the following data:

Sample ID	Lead Concentration (µg/wipe)	
	Trial 1	Trial 2
30 rotations	0.59	0.65
120 rotations	1.0	1.1

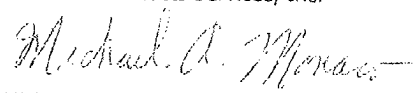
The results are reported in the table above as mass of lead per wipe

The information in this report is reported as **DATA ONLY**.

BVCPS Buffalo Contact Information for this Report:

Administrative Questions: Kathy Kubiak Phone: 716-505-3465 kathy.kubiak@us.bureauveritas.com
Technical Questions: Michael Monaco Phone: 716-505-3420 mike.monaco@us.bureauveritas.com

Bureau Veritas
Consumer Products Services, Inc.



Michael A. Monaco
Senior Project Engineer
Engineering Services Group

/jy

Note 1: This evaluation/analysis was performed at a Bureau Veritas Consumer Products Services, Inc. approved subcontract lab.

Note 2: At the request of the client, the report was revised to clarify the testing method used in this analysis.

Assessor's C.V.

Greg W. Gorder, PhD

Technology Sciences Group, Inc: 712 Fifth Street, Suite A; Davis, CA 95616
(530) 757-1281

Professional Experience:

Technology Sciences Group, Inc; Davis, CA **2000 – Present**

Senior Managing Scientist

- ***Proposition 65 Exposure Assessments:*** Has been assisting companies on all types of Proposition 65 matters since 2000. TSG's primary exposure assessor. In the past twelve months, has assessed oral, dermal, and inhalation exposures for multiple products covering at least 18 different chemicals.
- ***Consumer Product Volatile Organic Chemical (VOC) Requirements:*** Has been assisting companies with guidance on product VOC issues since 2000. States such as California limit consumer product VOC levels in in response to Federal Clean Air standards.
- ***Safer Consumer Product (SCP) Requirements:*** Has been tracking the development of states legislation targeting "green chemistry' principles for ingredient standards in consumer products for TSG and provides companies with SCP guidance.

Zeneca Ag Products; Richmond, CA **1989 – 1999**

Principle Research Scientist, Environmental Sciences Department

- ***Management***: Managed a team of four scientist conducting environmental fate studies under Good Laboratory Practice (GLP) for US Environmental Protection Agency (EPA) registration of new active ingredients.
- ***Study Expert:*** Selected Zeneca lead (Study Expert) for Plant Metabolism Studies. Dr. Gorder managed and directed numerous in-house and contracted studies and introduced methods to enhance report-writing efficiency including the development of report templates.
- ***Product Manager:*** Selected Environmental Sciences Product Manager for Roneet Herbicide. Dr. Gorder identified gaps in the EPA re-registration submission package, secured funds for three new studies and conducted Dietary Exposure Evaluation Modeling (DEEM) under the federal Food Quality Protection Act.

Dow Chemical; Walnut Creek, CA **1986 – 1989**

Senior Research Biochemist, Insecticide Discovery Biochemistry Section

- ***Insecticidal Bio-rational Leads:*** Contributed to identification and development of screening leads such as natural oils, spider venoms, and structural derivative synthesis. Dr. Gorder hosted seminars of experts to discuss areas of potential new insecticide chemistry and supported lead development by isolating the most insecticidal fractions of the oils and venoms for identification of active ingredients. His efforts on *Holena curta* venom were important in identifying Curtatoxin and co-authored a publication in the Journal of Biological Chemistry.

Postdoctoral Experience:

UC Berkeley; Berkeley, CA; Professor J. E. Casida **1983 – 1986**

Cornell University; Ithaca, NY; Professor C. F. Wilkinson **1980 – 1982**

- ***Novel Insecticidal Mechanism:*** Discovered that the organophosphorous insecticides phospholan and mephospholan are pro-insecticides that require metabolic activation. Dr. Gorder used model systems coupled with two dimensional Nuclear Magnetic Resonance (NMR) to identify the metabolic activation steps and novel alkylation (i.e., not phosphorylation) reaction with biological targets.
- ***Cytochrome P450 Structure-Activity Relationships:*** Identified hydroxylation rates and sites on toluene compounds (substituted in *ortho, meta, or para* positions with electron-donating or electron-withdrawing substituents) catalyzed by Phenobarbital-induced Cytochromes P450 under conditions of optimized Mechaelis-Menten kinetics.

Education:

PhD Entomology/Environmental Toxicology **1980**

- Iowa State University, Ames IA under Professor P. A. Dahm
- Dissertation: Carbofuran Persistence in Soil and Efficacy for Corn Rootworm Larval Control

MS Entomology **1976**

- University of Wisconsin, Madison, WI under E. P. Lichtenstein
- Thesis: Degradation of Parathion by Cranberry Soil Microorganism

BS Microbiology **1974**

- University of Wisconsin, Madison, WI senior thesis under J. Gregory Zeikus
- Senior Thesis: Effects of Pesticides on Methanogenesis in Mendota Lake Sediments

Publications:

Eight publications from 1980 – 1990 (seven as senior author) in journals that include Journal of Biological Chemistry, Bio-Organic Chemistry, Journal of Agricultural and Food Chemistry and Canadian Journal of Microbiology. Details are available on request.

ATTACHMENT 5

Duke University Medical Center
Department of Community & Family Medicine
Division of Occupational & Environmental Medicine
Box 3934
Durham, NC 27710
February 8, 2009

Bioaccessibility of Lead in Metal Pen Tips

Woodhall Stopford, MD, MSPH and Danielle Cappellini, B. Sc, MHA

Introduction

Metal point pens are made with milled tip components made of stainless steel, nickel silver or brass alloys that may contain in excess of 0.06% lead. Such tip components, however, can only be removed from pens or cartridges with tools and, therefore, do not pose an ingestion concern. Metal pen tips are not designed to be grasped during drawing and would only be expected to come into contact with skin or saliva by incidental contact. The following study addresses issues of whether absorption could occur in an age category of children (ages 6-12) who might use metal pens in a school setting. Ten types of metal pen tips were obtained from manufacturers in bulk. Nineteen pens were obtained at retail to determine exposed tip length. Tips were analyzed for total lead and for bioaccessible lead using synthetic sweat and synthetic saliva.

Methods

Total Lead: EPA SW-846 Method 6200 was used to test for lead content in bulk samples of pen tips by x-ray fluorescence (XRF). This is a nondestructive procedure and was originally developed for testing packaging to address issues of conformance with landfill ordinances (USEPA, 2007). For these analyses a Niton XL3t XFR (Thermo Fischer Scientific) laboratory unit was used. This method is sensitive to 2.5 ppm (microgram/g) lead and correlates well with destructive digestive methods and analysis by atomic absorption spectroscopy (Cappellini and Stopford, 2008)

Synthetic Sweat: A sweat equivalent salt mixture was prepared with technical grade reagents to conform with EN1811 (a synthetic sweat method used to test nickel containing materials that come into prolonged contact with skin) using the following salt proportions:

	g/L of DI Water
Urea	1
Sodium Chloride	5
Lactic Acid	940 microliters

pH was adjusted to 7.6 with a solution of ammonium hydroxide.

Synthetic Saliva: A saliva equivalent salt mixture was prepared with technical grade reagents to conform with DIN 53160 (a synthetic saliva method developed to determine extraction of dyes from articles) using the following salt proportions:

	g/L of DI Water
Sodium Bicarbonate	4.2
Sodium Chloride	0.5
Potassium Chloride	0.2

pH was adjusted to 7.3 with 2N HCl.

Lead extraction: Four to 8 pen tips from each batch were submersed in synthetic sweat and synthetic saliva (to make up approximately 1 gm of pen tips/per 50 ml of extractant) and extracted for 15 minutes. Pen tips were extracted at 37° C in the sweat solution without shaking. Pen tips were extracted in the saliva solution in a reciprocal shaker water bath at 37° C. Whether or not a shaker was used was based on the specifications in the synthetic sweat or saliva test methods. The extractants were then analyzed for lead by graphite furnace atomic absorption spectroscopy (EPA SW-846 Method 7421). This analytical method has a method detection of 1 ppm (1 microgram/g). Duplicate testing was done when detectable lead levels were found.

Tip length: The exposed length of each metal pen tip was measured to the nearest millimeter. Tips were then removed from the pens or cartridges and the total pen tip length was measured to the nearest millimeter. In each instance tools (pliers, hacksaw or knife) had to be used to remove the tips from the pens or cartridges.

Results

Results for total lead found in the pen tip samples and the results of extractions are summarized in the following table:

Table 1: Total and Bioaccessible Lead levels in Pen Tips

Metal Pen Tip Batch	Single Tip Weight (g)	XRF Lead Value (microgram/g)	Soluble Lead released per tip (micrograms)	Soluble Lead released per tip (micrograms)
			Synthetic sweat	Synthetic saliva
1	0.3001	25630	0.7-1.0	1.2/1.2
2	0.1439	27714	0.5-0.6	0.8-0.9
3	0.2270	1070	<0.3	<0.3
4	0.2250	1335	<0.3	<0.3
5	0.2166	1111	<0.3	<0.3
6	0.2721	13825	<0.3	<0.3
7	0.2197	21571	<0.3	<0.3
8	0.2836	15937	<0.3	<0.3
9	0.2193	22756	<0.3	<0.3
10	0.2725	18912	<0.3	<0.3

In the 19 pens, the exposed portion of the pen tip was 3-4 mm. The ratio of exposed length to total length of the pen tips was 0.34 ± 0.05 (1 sd). Release rates were adjusted to reflect the length of the tip that could come into contact with sweat or saliva by multiplying this ratio times the measured release rate for the entire tip.

When expressed in terms of microgram of lead release in one minute of contact, after adjusting for average length of the pen tip that is available for touching or mouthing, the results are as follows:

Table 2: Release rate (micrograms lead released in one minute of contact)

Metal Pen Tip Batch	Release rate to sweat (micrograms)	Release rate to saliva (micrograms)
1	0.016-0.021	0.027/0.027
2	0.011-0.013	0.019-0.021
3	<0.005	<0.005
4	<0.005	<0.005
5	<0.005	<0.005
6	<0.006	<0.006
7	<0.005	<0.005
8	<0.006	<0.006
9	<0.005	<0.005
10	<0.006	<0.006

Discussion

Choice of pH of extractant fluids

pH in axillary sweat has been found to approach that of serum (Burry et al., 2001). In adults blood pH averages 7.4 with children being found to have that blood pH by age 7-12 (Dong et al, 1985) with slightly lower pHs in younger children. Ecrine sweat glands in the palms are, however, shorter and palmar sweat can be slightly alkaline with an average pH of 7.6 with CO_2 equilibration in experimental animals (Goldsmith, 1983). This pH range is similar to that found in the palmar sweat of man where pH's can range to 7.5-7.8 (Kuno, 1956). A pH of 7.6 was chosen for this study.

The pH of saliva has been investigated in a study conducted by the National Institute of Public Health and the Environment of the Netherlands (RIVM, 1998), a study designed to investigate phthalate release from plastics when mouthed. The saliva pH of 3 groups of participants was measured with mean pH values ranging from 7.3-7.4. A pH of 7.3 was chosen for this study.

Lead release and exposure from contact with sweat and saliva

Although all pen tips tested contained >600 ppm total lead, less than 0.1% of the total lead was released in 15 minutes with exposure of the pen tips to synthetic saliva or sweat (Table 1) with no detectable release from 8 of 10 batches of pen tips. There was no correlation between total lead content and potential for lead release when pen tips came into contact with synthetic sweat or saliva.

When exposures were corrected to represent exposures to the exposed portion of the tip, exposures from skin contact or mouthing would be expected to be less than 0.03 micrograms in one minute of contact (Table 2), a non-detectable level.

Absorption from skin contact

Skin contact to metal pen tips does not occur during their use because the pens are always held well above the tip so that any contact would be incidental. Soluble lead salts can be absorbed with skin contact with absorption rates ranging from 0.00003-00025% per minute of the applied solution (Moore, et al. (1980). When absorption rates for soluble lead salts are taken into account, skin absorption from incidental contact to these metal pen tips would be as follows:

Table 3: Amount of lead absorbed in one minute of sweat contact

Metal Pen Tip Batch	Absorbed lead (micrograms)
1	<0.00000004
2	<0.00000003
3	<0.00000002
4	<0.00000002
5	<0.00000002
6	<0.00000002
7	<0.00000002
8x	<0.00000002
9	<0.00000002
10	<0.00000002

Since exposure would, at best, be incidental, exposure and absorption would be expected to be well less than the amounts found in this study after one minute of contact to synthetic sweat (Tables 2 and 3).

Absorption from mouthing

Mouthing of non-toy items is uncommon in 3 year old children and is not found in older children. RIVM (1998) found that such behavior occurred for 2 minutes of the waking day in 3 year old children. Freeman, et al. (2001) found, however, that from the age of 5-12 no mouthing of objects could be detected in any hour, a significant difference from children ages 3-4 where an average of 3 such incidents occurred each hour. Absorption efficiency of soluble lead from the gastrointestinal track is usually considered to be 40% for most models (Oomen, et al., 2003). The amount of lead absorbed from saliva contact to metal pen tips for one minute would be expected to be as follows:

Table 4: Amount of lead absorbed in one minute of saliva contact

Metal Pen Tip Batch	Absorbed lead (micrograms)
1	<0.012
2	<0.009
3	<0.002
4	<0.002
5	<0.002
6	<0.003
7	<0.002
8	<0.003
9	<0.002
10	<0.003

Since exposure would be incidental, exposure and absorption would be expected to be well less than the amounts found released after one minute of contact with synthetic saliva in this study (Tables 2 and 4).

Does lead absorption occur from use of pens?

Skin exposure to metal pen tips does not occur with normal use. If skin contact did occur, lead exposure would be in the non-detectable range, i.e., in the sub-microgram range as noted in Table 2 and absorption associated with such exposures would also be non-detectable, i.e., in the subpicogram range, well less than the amounts determined for one minute of sweat contact noted in Table 3.

Mouthing of non-toy objects is uncommon in 3 year old children and is not found in older children. Lead exposure would not be expected in older children from mouthing of metal pen tips. If mouthing occurred, lead exposure and absorption would be incidental and in the non-detectable range, i.e., in the submicrogram range, well less than the amounts determined for one minute of saliva contact noted in Tables 2 and 4.

Does lead absorption from use of metal pens present a public health risk?
California's Office of Environmental Health Hazard Assessment has completed a risk assessment for acceptable daily exposures to lead and has determined a maximum allowable dose level (absorbed lead) of 0.5 micrograms/day for the most sensitive endpoint (reproductive toxicity). Any possible exposures to lead from metal pen tips would be well below this level and, consequently, absorption of lead from incidental exposures to metal pen tips would not present a risk to public health.

Conclusions

Metal pen tips investigated in this study contained greater than 0.06% total lead but the amount that could be extracted with synthetic sweat or saliva was <0.1% of the total amount of lead present, being non-detectable in 80% of the batches tested. When corrected for the length of the pen tip that could come into contact with the skin or mouth, <0.03 micrograms of lead were found to be released in one minute of contact, an amount that is non-detectable. Since exposure would be incidental and only to the exposed portion of the pen tip, exposures would be expected to be well less than 0.03 micrograms a day, a non-detectable amount. The skin acts as an excellent barrier to absorption of soluble lead salts. Incidental skin exposure to metal pen tips would be expected to be associated with an absorbed dose of well less than 0.00000004 micrograms a day, a non-detectable amount. Exposures from incidental mouthing would be expected to be well less than 0.012 micrograms a day, a non-detectable amount. Absorption of lead from these incidental exposures would not present a public health risk.

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ATTACHMENT 6

ECHA
EUROPEAN CHEMICALS AGENCY

ANNEX XVII TO REACH – Conditions of restriction

Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Entry 63
Lead CAS No 7439-92-1 EC No 231-100-4 and its compound

Conditions of restriction
1. Shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0,05 % by weight. 2. For the purposes of paragraph 1: (i) 'jewellery articles' shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks; (ii) 'any individual part' shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles. 3. Paragraph 1 shall also apply to individual parts when placed on the market or used for jewellery-making. 4. By way of derogation, paragraph 1 shall not apply to: (a) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Council Directive 69/493/EEC (*); (b) internal components of watch timepieces inaccessible to consumers; (c) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103, as established by Regulation (EEC) No 2658/87), unless they have been treated with lead or its compounds or mixtures containing these substances; (d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C. 5. By way of derogation, paragraph 1 shall not apply to jewellery articles placed on the market for the first time before 9 October 2013 and jewellery articles produced before 10 December 1961.

6. By 9 October 2017, the Commission shall re-evaluate this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 1 and, if appropriate, modify this entry accordingly.

7. Shall not be placed on the market or used in articles supplied to the general public, if the concentration of lead (expressed as metal) in those articles or accessible parts thereof is equal to or greater than 0,05 % by weight, and those articles or accessible parts thereof may, during normal or reasonably foreseeable conditions of use, be placed in the mouth by children.

That limit shall not apply where it can be demonstrated that the rate of lead release from such an article or any such accessible part of an article, whether coated or uncoated, does not exceed 0,05 µg/cm² per hour (equivalent to 0,05 µg/g/h), and, for coated articles, that the coating is sufficient to ensure that this release rate is not exceeded for a period of at least two years of normal or reasonably foreseeable conditions of use of the article.

For the purposes of this paragraph, it is considered that an article or accessible part of an article may be placed in the mouth by children if it is smaller than 5 cm in one dimension or has a detachable or protruding part of that size.

8. By way of derogation, paragraph 7 shall not apply to:

(a) jewellery articles covered by paragraph 1;
(b) crystal glass as defined in Annex I (categories 1, 2, 3 and 4) to Directive 69/493/EEC;
(c) non-synthetic or reconstructed precious and semi-precious stones (CN code 7103 as established by Regulation (EEC) No 2658/ 87) unless they have been treated with lead or its compounds or mixtures containing these substances;
(d) enamels, defined as vitrifiable mixtures resulting from the fusion, vitrification or sintering of mineral melted at a temperature of at least 500 ° C;
(e) keys and locks, including padlocks;
(f) musical instruments;
(g) articles and parts of articles comprising brass alloys, if the concentration of lead (expressed as metal) in the brass alloy does not exceed 0,5 % by weight;
(h) the tips of writing instruments;
(i) religious articles;
(j) portable zinc-carbon batteries and button cell batteries;
(k) articles within the scope of:

(i) Directive 94/62/EC;

(ii) Regulation (EC) No 1935/2004;

(iii) Directive 2009/48/EC of the European Parliament and of the Council (**);

(iv) Directive 2011/65/EU of the European Parliament and of the Council (***)

9. By 1 July 2019, the Commission shall re-evaluate paragraphs 7 and 8(e), (f), (i) and (j) of this entry in the light of new scientific information, including the availability of alternatives and the migration of lead from the articles referred to in paragraph 7, including the requirement on coating integrity, and, if appropriate, modify this entry accordingly.

10. By way of derogation paragraph 7 shall not apply to articles placed on the market for the first time before 1 June 2016.

11. Doing either of the following acts after 15 February 2023 in or within 100 metres of wetlands is prohibited:

(a) discharging gunshot containing a concentration of lead (expressed as metal) equal to or greater than 1 % by weight;

(b) carrying any such gunshot where this occurs while out wetland shooting or as part of going wetland shooting.

For the purposes of the first subparagraph:

(a) "within 100 metres of wetlands" means within 100 metres outward from any outer boundary point of a wetland;

(b) "wetland shooting" means shooting in or within 100 metres of wetlands;

(c) if a person is found carrying gunshot in or within 100 metres of wetlands while out shooting or as part of going shooting, the shooting concerned shall be presumed to be wetland shooting unless that person can demonstrate that it was some other type of shooting.

The restriction laid down in the first subparagraph shall not apply in a Member State if that Member State notifies the Commission in accordance with paragraph 12 that it intends to make use of the option granted by that paragraph.

12. If at least 20 % in total of the territory, excluding the territorial waters, of a Member State are wetlands, that Member State may, in place of the restriction laid down in the first subparagraph of paragraph 11, prohibit the following acts throughout the whole of its territory from 15 February 2024:

(a) the placing on the market of gunshot containing a concentration of lead (expressed as metal) equal to or greater than 1 % by weight;

(b) the discharging of any such gunshot;

(c) carrying any such gunshot while out shooting or as part of going shooting.

Any Member State intending to make use of the option granted by the first subparagraph shall notify the Commission of this intention by 15 August 2021. The Member State shall communicate the text of the national measures adopted by it to the Commission without delay and in any event by 15 August 2023. The Commission shall make publicly available without delay any such notices of intention and texts of national measures received by it.

13. For the purposes of paragraphs 11 and 12:

(a) "wetlands" means areas of marsh, fen, peatland or water, whether natural or artificial, permanent or temporary, with water that is static or flowing, fresh, brackish or salt, including areas of marine water the depth of which at low tide does not exceed 6 metres;

(b) "gunshot" means pellets used or intended for use in a single charge or cartridge in a shotgun;

(c) "shotgun" means a smooth-bore gun, excluding airguns;

(d) "shooting" means any shooting with a shotgun;

(e) "carrying" means any carrying on the person or carrying or transporting by any other means;

(f) in determining whether a person found with gunshot is carrying gunshot "as part of going shooting":

(i) regard shall be had to all the circumstances of the case;

(ii) the person found with the gunshot need not necessarily be the same person as the person shooting.

14. Member States may maintain national provisions for protection of the environment or human health in force on 15 February 2021 and restricting lead in gunshot more severely than provided for in paragraph 11.

The Member State shall communicate the text of those national provisions to the Commission without delay. The Commission shall make publicly available without delay any such texts of national provisions received by it.

(*) OJ L 326, 29.12.1969, p. 36.
(**) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).
(***) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88).

ATTACHMENT 7

October 24, 2024

To: David Baker
Writing Instrument Manufacturers Association

From: Elliot Sigal, Intrinsik Corp.

Re: Assessment of Potential Risks of Lead in Pen Tips to Freshwater Aquatic Life and Recreational Water Use in Minnesota

Background

All ballpoint pens sold throughout the world contain small amounts of the heavy metal lead, which is essential in order to create high-quality components, including pen points. Most pen points have a total lead content in excess of 2,500 parts per million (ppm).

Minn. Stat. § 325E.3892 (the 'Statutue') states that a person or business cannot "import, manufacture, sell, hold for sale, distribute or offer for use" in the state of Minnesota any product containing lead at more than 0.0009 percent by total weight (90 ppm). As the Statute is currently written and potentially enforced, it appears to encompass all writing instruments, including ballpoint pens, which are pervasively sold and utilized throughout the state of Minnesota.

Consequently, the restrictions imposed by the Statute threaten to prohibit the sale and use of most ballpoint pens currently available in the state of Minnesota, as there are no feasible alternative materials available to replace the limited amount of lead utilized in the manufacture of these writing instruments.

While the Statute seeks to protect consumers and the environment from the potential effects of lead exposure, the Statute imposes restrictions which extend to products that pose no quantifiable threat of lead exposure. The Statute does not attempt to limit the scope of the prohibition to products which may cause harm and simply focuses on the material content of the products and their components, presuming some undefined level of exposure and risk. As a result, consumers in the state of Minnesota, including businesses, private and public offices, government agencies, schools and universities which rely heavily on the use of ballpoint pens will be deprived of these essential tools when the Statute is fully implemented.

Intrinsik Corp. (Intrinsik) was retained by the Writing Instrument Manufacturers Association (WIMA) to conduct an assessment of the potential risks of lead in pen tips to the environment. The assessment quantifies potential exposure and resulting risks under a conservatrive exposure scenario where 50 million pens are assumed to be sold and discarded every year in the State of Minnesota. The potential for lead in the discarded pens to be released into the environment was evaluated. The primary 'pathway' of concern was considered to be the protential for release of lead from landfill sites in the State into nearby waterbodies, potentially harming freshwater aquatic life and impacting recreational use of the waterbodies. The methodology, results and conclusions of this assessment are summarized in this memo which is intended to support the exemption of ballpoint pens from the Statutue.

Methodology

To assess the potential risks of lead in pen tips to aquatic life in Minnesota, lead exposure resulting from the use and disposal of 50 million pens (expressed as the annual loading rate) was calculated for a surrogate waterbody in the state of Minnesota (i.e., Littlefork River) and the predicted exposure was compared to Minnesota's water quality standards as described in Minnesota Rules chapters 7050 (Waters of the State). The Class 2 standards, protective of aquatic life and recreation, were selected as the appropriate standards for this comparison. These standards were developed to protect ecosystems, habitats, and aquatic biota including fish, insects, mollusks, crustaceans, plans, microscopic organisms, and all other aquatic-dependent organisms, as well as recreational uses such as swimming, fishing, hunting, and boating (MPCA, 2024).

The Class 2 standards are divided into subclassess as follows:

- Class 2A: Cold water habitat – lakes and streams
- Class 2B: Warm water habitat – lakes and streams
- Class 2Bd: Warm water habitat also protected as a source for drinking water – lakes and streams
- Class 2D: Wetlands

As described in the Minnesota Rules Chapter 7050 (State of Minnesota, 2023), the water quality standard for lead that is protective of chronic effects to aquatic life for all of the subclasses listed above was adopted from the U.S. Environmental Protection Agency (EPA) National Recommended Water Quality Criteria (NRWQC). The NRWQC represent the highest concentrations of contaminants in water that are not expected to pose a significant risk to the majority of species in a given environment or a narrative description of the desired conditions of a water body being "free from" certain negative conditions (U.S. EPA, 2024).

Both the State of Minnesota and the U.S. EPA recommend using the dissolved metal criteria over the total metal criteria because dissolved metals more closely approximate the bioavailable fraction of metals in the water column. The Class 2 chronic standard for dissolved lead (equivalent to the chronic freshwater NRWQC for dissolved lead) is hardness-dependent and is expressed using the following equation:

Chronic Standard (dissolved) = {exp(1.273 [ln(hardness)] -4.705)} (1.46203-[(ln(hardness))(0.145712)])

Using the above equation, and a mean water hardness of 192 mg/L for the state of Minnesota (HydroFLOW USA, 2024), the resulting chronic standard is 5.1 µg/L dissolved lead.

A series of exposure calculations were completed in order to predict the lead exposure resulting from the use and disposal of 50 million pens (expressed as the annual loading rate) in a landfill adjacent to the Littlefork River.

Firstly, the lead concentration per pen (expressed as µg/mL) was determined using the following equation:

$$CONC_{lead}\ \left(\frac{\mu g}{mL}\right) = \frac{MPTW\ (g) \times LC\left(\frac{\mu g}{g}\right) \times\ BN(\%)\ \times BP(\%)\ \times MR(\%)}{E\ (mL)}$$

Where:

$CONC_{lead}$ = Lead concentration per pen (µg/mL)
MPTW = metal pen tip weight (g)
LC = Lead content of tip (µg/g)
BN = Percent of ball-point pens with brass nibs (%)
BP = Percent of pens that are ball-point (%)
MR = Maximum release rate of lead (per 15 minutes) (%)
E = Extract per pen (mL)

Secondly, the lead concentration for 50 million pens was determined using the following equation:

$$CONC_{lead}50M\ (\frac{g}{mL}) = \frac{CONC_{lead}(\frac{\mu g}{mL})\ \times\ N}{UC(\frac{\mu g}{g})}$$

Where:

$CONC_{lead}50M$ = Lead concentration for 50 million pens (g/mL)
$CONC_{lead}$ = Lead concentration per pen (µg/mL)
N = Total number of pens sold in the state of Minnesota (50 Million; Haws-KM, 2024)
UC = Unit conversion (µg/g)

Thirdly, the annual flow rate of the Littlefork River (expressed as L/year) was determined using the following equation:

$$AFR\ (L/year) =\ FR\ \left(\frac{ft^3}{s}\right) \times UC1\left(\frac{L}{ft^3}\right) \times UC2\left(\frac{s}{min}\right) \times UC3\ \left(\frac{min}{hr}\right) \times UC4\ \left(\frac{hr}{day}\right) \times\ UC5\ \left(\frac{days}{year}\right)$$

Where:

AFR = Annual flow rate (L/year)
FR = Flow rate of the Littlefork River (ft^3/s)
UC1 = Unit conversion 1 (L/ft^3)
UC2 = Unit conversion 2 (s/min)
UC3 = Unit conversion 3 (min/hr)
UC4 = Unit conversion 4 (hr/day)
UC5 = Unit conversion 5 (days/year)

Lastly, the annual loading of lead to the Littlefork River (expressed as µg/L) was determined using the following equation:

$$ALR\ (\frac{\mu g}{L}) = \frac{CONC_{lead}50M\left(\frac{g}{mL}\right)}{AFR\ \left(\frac{L}{year}\right)} \times \text{UC1}\ \left(\frac{mL}{L}\right) \times \text{UC2}\ \left(\frac{\mu g}{g}\right)$$

Where:

ALR	= Annual loading rate (µg/L)
$CONC_{lead}$50M	= Lead concentration for 50 million pens (g/mL)
AFR	= Annual flow rate (L/year)
UC1	= Unit conversion 1 (mL/L)
UC2	= Unit conversion 2 (µg/g)

Following the calculation of the annual loading rate, this predicted exposure level was compared to the state-specific chronic water quality standard for dissolved lead.

Assessment Results

The following section presents the calculations for the annual loading of lead to the Littlefork River.

Lead concentration per pen (expressed as µg/mL)

$$CONC_{lead}\ (\frac{\mu g}{mL}) = \frac{MPTW\ (g) \times LC\left(\frac{\mu g}{g}\right) \times\ BN(\%)\ \times BP(\%)\ \times MR(\%)}{E\ (mL)}$$

$$CONC_{lead}\ (\frac{\mu g}{mL})\ = \frac{0.238\ (g) \times 5{,}000\left(\frac{\mu g}{g}\right) \times\ 85\%\ \times 85\%\ \times 0.1\%}{10\ mL}$$

$$CONC_{lead}\ = 0.09\ \mu g/mL$$

Where:

$CONC_{lead}$	= Lead concentration per pen (µg/mL)
MPTW	= metal pen tip weight (0.238 g); representing mean metal pen tip weight from 10 pens (Duke 2009)
LC	= Lead content of tip (5,000 µg/g); 2.5-5% (WIMA, 2009)
BN	= Percent of ball-point pens with brass nibs (85%) (WIMA, 2009)
BP	= Percent of pens that are ball-point (85%) (WIMA, 2009)
MR	= Maximum release rate of lead (per 15 minutes) (0.1%); sweat and saliva extractions based on 1 g of pen tip/50 mL of extractant (Duke 2009)
E	= Extract per pen (10 mL); based on extract of 50 mL for 5 pens (Duke 2009)

Lead concentration for 50,000,000 pens (g/mL)

$$LC50M\ (\frac{g}{mL}) = \frac{LC\ (\frac{\mu g}{mL})\ \times\ N}{UC(\frac{\mu g}{g})}$$

$$LC50M = \frac{0.09\ (\frac{\mu g}{mL})\ \times\ 50{,}000{,}000}{1{,}000{,}000\ (\frac{\mu g}{g})}$$

$$LC50M = 4.3\ g/mL$$

Where:

$CONC_{lead}$50M = Lead concentration for 50 million pens (g/mL)

$CONC_{lead}$ = Lead concentration per pen (0.09 µg/mL)

N = Total number of pens sold in the state of Minnesota (50,000,000)

UC = Unit conversion (1,000,000 µg/g)

Annual flow rate of the Littlefork River (expressed as L/year)

$$AFR\ (L/year) =\ FR\ \left(\frac{ft^3}{s}\right) \times UC1\left(\frac{L}{ft^3}\right) \times UC2\left(\frac{s}{min}\right) \times UC3\ \left(\frac{min}{hr}\right) \times UC4\ \left(\frac{hr}{day}\right) \times\ UC5\ \left(\frac{days}{year}\right)$$

$$AFR =\ 870\ \left(\frac{ft3}{s}\right) \times 28.3\left(\frac{L}{ft3}\right) \times 60\ \left(\frac{s}{min}\right) \times 60\ \left(\frac{min}{hr}\right) \times 24\ \left(\frac{hr}{day}\right) \times\ 365\ \left(\frac{days}{year}\right)$$

$$AFR =\ 776{,}908{,}786{,}176\ L/year$$

Where:

AFR = Annual flow rate (L/year);

FR = Flow rate of the Littlefork River (870 ft^3/s); mean flow rate based on 104 years of data (U.S. Geological Survey, 2024)

UC1 = Unit conversion 1 (28.3 L/ft^3)

UC2 = Unit conversion 2 (60 s/min)

UC3 = Unit conversion 3 (60 min/hr)

UC4 = Unit conversion 4 (24 hr/day)

UC5 = Unit conversion 5 (365 days/year)

Annual loading of lead to the Littlefork River (expressed as µg/L)

$$ALR\ (\frac{\mu g}{l}) = \frac{CONC_{lead}50M\left(\frac{g}{mL}\right)}{AFR\ \left(\frac{L}{year}\right)} \times \text{UC1}\left(\frac{mL}{L}\right) \times \text{UC2}\left(\frac{\mu g}{g}\right)$$

$$ALR = \frac{4.3\frac{g}{mL}}{776{,}908{,}786{,}176\ L/year} \times 1{,}000\left(\frac{mL}{L}\right) \times 1{,}000{,}0000\left(\frac{\mu g}{g}\right)$$

$$ALR = \ 0.0055\ \mu g/L$$

Where:

ALR = Annual loading rate (µg/L)

$CONC_{lead}$50M = Lead concentration for 50 million pens (4.3 g/mL)

AFR = Annual flow rate (776,908,786,176 L/year)

UC1 = Unit conversion 1 (1,000 mL/L)

UC2 = Unit conversion 1 (1,000,000 µg/g)

Uncertainties

The following assumptions should be noted:

- 50 million pens are sold per year in the State of Minnesota
- All pens are disposed of each year
- All disposed pens are placed in a single landfill in the State of Minnesota; according to a recent newspaper article, there are 21 operational landfill sites in Minnesota. In addition, there are 7 incinerators in Minnesota for municipal solid waste (https://www.startribune.com/talking-trash-should-minnesota-burn-or-bury-our-garbage/601144554)
- Uncontrolled releases from the landfill are discharged into a single waterbody continually over the course of a year
- Littlefork River was selected as a representative waterbody in the State of Minnesota
- Lead content of pens tip typically range between 2.5-5%; 5000 µg/g (5%) was assumed for all pen tips
- 85% of ball-point pens were assumed to have brass tips containing lead
- 85% of pens sold in Minnesota were assumed be ball-point pens
- The release of lead from the pen tips was based on simulated saliva and sweat extraction studies; landfill leachate characteristics may differ and result in high levels of extraction

Conclusions

As presented above, the estimated annual loading rate of lead from 50 million pens to the Littlefork River is 0.0055 µg/L which is approximately 900x lower than the state-specific water quality standard (5.1 µg/L) protective of chronic effects to freshwater aquatic life, as well as recreational water uses such as swimming, fishing, hunting, and boating. Based on the available data and the assumptions used in the assessment, the use and disposal of 50 million pens containing lead is not considered to pose a potential risk to freshwater aquatic life or recreational water use in the State of Minnesota. This assessment is considered to be conservative given that it is highly unlikely the exposure of lead from all pens used in the state of Minnesota will occur within a single waterbody.

Intrinsik Corp.

Elliot Sigal, B.Sc. (Hon.), QPRA, UKRT, ERT
Vice President/Senior Toxicologist

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Haws-KM

Via Email

March 24, 2025 ***Reply to St. Paul***

Rep. Josh Heintzeman
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Re: The Arts and Creative Materials Institute, Inc.'s Letter to the House Environment and Natural Resources Finance and Policy Committee in Support of Minnesota House Bill HF737, Amending Minn. Stat. 325E.3892, Lead and Cadmium in Consumer Products; Prohibition.

Dear Rep. Heintzeman and Rep. Fischer:

Our firm represents The Arts and Creative Materials Institute, Inc. (ACMI). ACMI is an international association of more than 200 art, craft and creative material manufacturers, distributors and retailers promoting safety in art and creative products through its certification program. For over 80 years, ACMI has instituted a program for the evaluation and certification of children's art materials to confirm that the products submitted for certification are non-toxic. ACMI's certification program was expanded in 1982 to broaden the range of art materials reviewed and to include adult products. ACMI retains toxicologists to evaluate art materials, including materials containing cadmium and lead, using the ASTM D-4236 standard. The standard addresses the potential hazards resulting from exposure to various substances and proscribes cautionary labeling to address those potential hazards.

ACMI has significant concerns with the cadmium and lead restrictions imposed by Minn. Stat. 325E.3892 (the Statute) relating to art supplies. The vague and overbroad language of the Statute suggests that its enforceability will lead to a complete ban on cadmium and lead containing oils, watercolors, temperas, pastels, ceramic glazes, stains and pigments,

both powder and liquid, in the state of Minnesota. These products offer lightfastness and durability that is essential to professional artists and to the art industry in Minnesota. A ban of these products will have an indiscriminate effect to Minnesota's professional artists, art museums, art supply stores, art schools and residents in Minnesota. Minnesota is the only place in the country with such a broad and all-encompassing ban. Therefore, ACMI respectfully requests that professional artists' supplies be exempted from the Statute.

As background, cadmium and lead containing art supplies contain cadmium and lead elements that exceed the limits imposed by the Statute. However, despite the presence of cadmium and lead elements in these professional artists' supplies, there is no data indicating that these limited exposures cause public health risks, including to children. In contrast, the available data suggests that any public health risk is negligible and that the restrictions of cadmium and lead in professional artists' paints and pigments would have minimal impact to children's health, and to public health in general. These studies and accompanying opinions have been provided to the Minnesota Pollution Control Agency (MPCA). Copies of these studies have also been included with this letter for reference. It is important to note that the cadmium content in art supplies is encapsulated and not generally bioavailable. The public concerns the Statute seeks to cure are best addressed through a data-backed regulatory scheme that focuses on products that expose the public to significant levels of cadmium and lead and that have shown to be harmful to public health.

Notably, cadmium and lead containing professional art supplies such as oils, watercolors, temperas, pastels, ceramic glazes, stains and pigments, both powder and liquid, have been used for centuries and are part of many of the great works of art we know today, including those we see regularly in our day-to-day lives in museums, churches, homes, offices and other public and private spaces. These professional art supplies continue to be essential to artists in their day-to-day work. The ban injures not only individual professional artists, but also art schools, museums, universities and other independent art studies across the state.

While some "alternative" non-cadmium and lead-free oils, watercolors, temperas, pastels, ceramic glazes, stains and pigments exist, these substitutes are not suitable alternatives because these do not provide the same degree of qualities of color vividness and lightfastness.

Therefore, the only reasonable solution, considering the available scientific evidence and lack of feasible alternatives, is to exempt professional artists' supplies from the reach of the Statute. Failure to provide an exception for these supplies will result in their total prohibition. Such a result is unfair not only to professional artists and the art industry, but to all Minnesota residents who rely on the availability of these products.

For all the reasons stated above, we kindly request that the House Commerce Finance and Policy Committee support and adopt Minnesota House Bill HF737 to amend Minn. Stat. 325E.3892 to exclude artists' supplies from the Statute.

Thank you for your time and attention.

/s/ *William L. Moran*

William L. Moran
Attorney at Law
Haws-KM, P.A.

Enclosures

ATTACHMENT 1

Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on

Cadmium and its compounds in Artist's Paints

ECHA/RAC/RES-O-0000004990-69-02/F

Adopted

26 November 2014

ECHA/RAC/RES-O-0000004990-69-02/F

26 November 2014

Opinion of the Committee for Risk Assessment

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**Cadmium and its compounds (in Artist paints)**
EC No.:	231-152-8 (Cadmium)
CAS No.:	7440-43-9 (Cadmium)

This document presents the opinion adopted by RAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINION

Sweden has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at **http://echa.europa.eu/web/guest/restrictions-under-consideration** on 19 March 2014. Interested parties were invited to submit comments and contributions by 19 September 2014.

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC:	**Frank Jensen**
Co-rapporteur, appointed by RAC:	**Urs Schlüter**

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on 26 November 2014.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The RAC opinion was adopted ***by consensus*** of all members having the right to vote.

OPINION

The originally proposed restriction by the Dossier Submitter is:

Cadmium (CAS No. 7440-43-9, EG No. 231-152-8) and its compounds

1. Shall not be placed on the market or used in:
   - artists' paints TARIC code [3213]
   - pigments, TARIC code [3212] used in the manufacture of artists' paints.
2. For artists' paints or pigments used in the manufacture of artists' paints containing zinc with a zinc content exceeding 10 % by weight of the paint or the pigment, the concentration of cadmium (expressed as Cadmium metal) shall not be equal or greater than 0,1 % by weight.
3. Member States may exempt the placing on the market, manufacture and use of artists` paints and pigments from paragraph 1 for restoration and maintenance of works of art and historic buildings and their interior.

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction is not justified because in reducing the risks from cadmium in artists' paints alone, this restriction under REACH is not considered to be the most appropriate EU wide measure to address the negligible level of risk identified by RAC in terms of its effectiveness. RAC notes however, that the proposed measure would be efficient if it is considered necessary to address this minor contribution to the overall cadmium input across the EU.

JUSTIFICATION FOR THE OPINION OF RAC

IDENTIFIED HAZARD AND RISK

The restriction proposed by the Dossier Submitter is based on the following assumptions:

- Cadmium pigments in artists' paints released to waste water will to some extent end up in the sewage sludge at the waste water treatment plant (WWTP). Some of the sludge is then used as a fertiliser in agriculture. As described in section B.4, of the Background Document, the cadmium compounds contained in the pigments used in artists' paints will eventually dissolve in the soil and hence there is a potential crop uptake and consequently exposure to humans via food.

- If the cadmium input originating from artists' paints is removed, the average intake via food over 100 years is estimated to be reduced by 0.001 µg cadmium / day (compared to baseline), which is equivalent to 0.006% of the total intake via food. About 0.003 % decrease is expected after 50 years.

- EFSA has in 2009 expressed concern that the margin between the average weekly intake of cadmium from food by the general population and the health-based guidance values is too small. EFSA therefore suggest that exposure to cadmium at population level should be reduced.

- The toxicity of all cadmium compounds is related to the Cd(II) ion. For long-term effects, also less soluble cadmium compounds contribute to the pool of cadmium that humans are exposed to. The biological half-life of cadmium in humans is extremely long (10-30 years) and the body burden of cadmium therefore increases, mainly via accumulation in the kidney, during the entire life span of an individual. This means that most toxic effects occur in the later part of life, when the body burden of cadmium has reached a critical level.

- The risk estimation from EFSA is based on effects on kidney function. But more recent research has pointed out osteoporosis as a serious effect of cadmium exposure which may occur at even lower exposure levels compared to the kidney effects. More recent studies also suggest an association between cancer and cadmium exposure. The dossier submitter chose to perform quantitative risk assessments using two different endpoints, i.e. bone fractures in males and females more than approximately 50 years of age and postmenopausal breast cancer.

- In 150 years from now, the reduction of number of incidences are calculated to be:

    - 48 bone fractures per year (37 in females and 11 in males);
    - 13 cases of breast cancer/per year;

  based on emissions of 0.11 tonnes of cadmium to agricultural land from artists' paints via sludge.

- Alternatives, i.e. colours, imitating cadmium, already exist. Cadmium based pigments are mainly substituted by organic pigments. The properties (from an artists point of view, not from a toxicological perspective) of the organic pigments are in many ways similar to cadmium colours but cannot be considered identical and thus have to be evaluated on a case- by- case basis by the individual artist.

This opinion considers the evidence presented in the restriction dossier and comments submitted during public consultation and RAC discussions.

Description of the risk to be addressed by the proposed restriction

- Information on hazard(s)

Only human health hazards are considered for this proposal.

The harmonised classification is shown below (Table 11 from the BD).

Table 1. *Harmonised classification of cadmium Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008*

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling	
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram Signal Word Code(s)	Hazard Statement Code(s)
048-002-00-0	Cadmium (non-pyrophoric)	231-152-8	7440-43-9	Carc. 1B Muta. 2 Repr. 2 Acute Tox. 2 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H350 H341 H361fd H330 H372 H400 H410	GHS06 GHS08 GHS09 Dgr	H350 H341 H361fd H330 H372 H410

H350: May cause cancer.
H341: May cause genetic defects.
H361fd: May damage fertility. May damage the unborn child.
H330: Fatal if inhaled.
H372: Causes damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Some of the cadmium compounds (like cadmium sulphate and cadmium fluoride) have a more stringent CMR-classification as Carc. 1B, Mut. 1B and Repr. 1B.

The dossier submitter has focused in their proposal on the effects of cadmium on the kidney (as documented by EFSA) and on bone fracture and cancer (in particular breast cancer); these effects are discussed below.

The toxicity of all cadmium compounds is related to the Cd(II) ion. For long-term effects, also less soluble cadmium compounds contribute to the pool of cadmium that humans are exposed to. The biological half-life of cadmium in humans is extremely long (10-30 years) and the body burden of cadmium therefore increases, mainly via accumulation in the kidney, during the entire life span of an individual. This means that most toxic effects occur in the later part of life, when the body burden of cadmium has reached a critical level. The long half-life also means that once these critical levels have been attained, and effects occur, they are in practice irreversible due to continued internal exposure.

RAC observes that the toxic properties which cause the harmful effects are related to the Cd(II) ion. Therefore the degredation of the pigments is important (see later). Cadmium accumulates in humans due to the long biological half-time and therefore the exposure through the whole life is relevant.

Adressing the EFSA opinions on Cadmium in food

EFSA (2012) stated (slightly edited for readability):

"The general population is exposed to cadmium from multiple sources, including smoking, but in the non-smoking general population food is the dominant source. Cadmium is primarily toxic to the kidney, but can also cause bone demineralisation and has been statistically associated with increased risk of cancer in the lung, endometrium, bladder, and breast.

In 2009 and subsequently confirmed in 2011, the Panel on Contaminants in the Food Chain issued an opinion in which they recommended that the PTWI [Provisional Tolerable Weekly Intake] of 7 µg/kg body weight should be reduced to a tolerable weekly intake (TWI) of 2.5 µg/kg body weight in order to ensure a high level of protection of all consumers, including exposed and vulnerable subgroups of the population.

A Provisional Tolerable Weekly Intake (PTWI) for cadmium of 7 µg/kg body weight was establishedby the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1988. In 2010, the JECFAreviewed its previous evaluation and established a provisional tolerable monthly intake (PTMI) of 25µg/kg body weight corresponding to a weekly intake of 5.8 µg/kg body weight. In 2009 andsubsequently confirmed in 2011, the Panel on Contaminants in the Food Chain issued an opinion inwhich they recommended that thePTWI should be reduced to a tolerable weekly intake (TWI) of 2.5µg/kg body weight in order to ensure a high level of protection of all consumers, including exposedand vulnerable subgroups of the population.

In 2011 the CONTAM Panel of EFSA stated*: Based on the current state of knowledge, the CONTAM Panel concluded that for cadmium the currentTWI of 2.5 µg/kg b.w. established in 2009 should be maintained in order to ensure a high level ofprotection of consumers, including subgroups of the population such as children, vegetarians or peopleliving in highly contaminated areas. Taking non-dietary exposure into account, it is anticipated that thetotal exposure of some subgroups of the population could exceed the JECFA PTMI as well as theCONTAM TWI.*

The CONTAM Panel reaffirmed its previous conclusion that adverse effects are unlikely to occur in an individual with current dietary exposure, but there is a need to reduce exposure to cadmium at thepopulation level.

By using the more detailed and refined food consumption information now available the average middle bound lifetime cadmium dietary exposure for the European population as a whole is estimated at 2.04 µg/kg body weight per week. It was highest in toddlers with an average of 4.85 µg/kg body weight per week and lowest in the elderly population group at 1.56 µg/kg body weight per week. Potential 95th percentile middle bound lifetime exposure, with the assumption that the same individuals retained high exposure throughout life, was estimated at 3.66 µg/kg body weight per week with a high of 8.19 µg/kg body weight per week for toddlers and a low of 2.82 µg/kg body weight per week for the elderly.

Often it is not the food with the highest cadmium levels, but foods that are consumed in larger quantities that have the greatest impact on cadmium dietary exposure. This was true as the broad food categories of grains and grain products (26.9%), vegetables and vegetable products (16.0%) and starchy roots and tubers (13.2%) were identified as major contributors to the cadmium dietary exposure.

The EFSA Panel concluded that although adverse effects are unlikely to occur in an individual with current dietary exposure, there is a need to reduce exposure to cadmium at the population level because of the limited safety margin".

The current review [EFSA 2012] confirmed *"that children on average and adults at the 95th*

percentile dietary exposure could exceed health-based guidance values." RAC also recognises that the EFSA Panel opinion was extensively discussed (also in their public consultation) and not all stakeholders (including some member states) are on the same line as stated in the opinion regarding e.g. dietary intake and Cd levels in humans.

The dossier submitter has not questioned these conclusions and has used them as a basis for the proposed restriction.

Conclusion 1:

RAC has no information that contradicts the overall conclusions made by EFSA (2012) "that children on average and adults at the 95th percentile dietary exposure could exceed health-based guidance values." Regarding the PTWI, RAC notes the different values between WHO and EFSA but has no information that would contradict the conclusion made by EFSA. Input from the public consultations (International Cadmium Association, ICdA) suggests that the time trends in Cd intake in the future will decrease with 15% over the next 100 years. Information about a decrease in average urinary levels is also mentioned. RAC cannot validate this information based on the data presented.

Bone fracture and breast cancer

The dossier presents data, calculations and discussions regarding other effects than kidney effects. The focus is on bone fractures and breast cancer.

If the cadmium originating from artist paints is removed, it will – according to the background document – in 150 years from now result in a yearly reduction of:

- 37 bone fractures in females;
- 11 bone fractures in males and;
- 13 cases of breast cancer.

The time frame of 150 years is based on an assessment on when the proposed restriction will reach its full effects.The most important reasons for this are the time needed for cadmium to move from the sludge to the crop (can take decades) and the extremely long human half-life (up to 40 yrs), which means that cadmium accumulates in the body and toxic concentrations are mostly attained late in life (> 50 years of age).

Such long time scales are rare but were used before e.g. when modelling long-term changes in soil concentrations in the discussions of the amendment of the fertilizers regulation (EG 2003/2003).

Some of the conclusions in the background document regarding hazard are:

"A reason for not choosing kidney effects for the quantitative risk assessment in the present Annex XV report is the ongoing debate on the suitability of measuring exposure and effects in the same matrix (i.e. urine) at very low exposure levels. Further, it was also considered difficult to assess and quantify the long-term health effects of minor tubular damage. It needs to be emphasized though, that kidney effects are an important part of the risk panorama of cadmium and thus adds to the risks calculated for other end-points. Although most effects in the general population are expected to occur later in life (due to the accumulation of cadmium in the body over the years), recent studies also indicate possible developmental effects.

The chosen studies on bone effects and breast cancer are from Sweden. They have been used because we consider them to be the most appropriate ones when evaluating effects in the general population by dietary cadmium exposure. The studies used large prospective population-based cohorts of the general Swedish population. The participation rates were

relatively high allowing generalization of the results to the Swedish population.

We consider the results also to be relevant for the EU population:

- *The dietary exposure to cadmium in Sweden is similar to the average EU exposure (EFSA 2012).*
- *The incidences of breast cancer in EU countries vary with a factor 2-3. The data from Sweden is in the middle of this range.*
- *For fractures, the incidences in Sweden are higher than in most other EU countries. The reason for the higher incidence in the northern part of Europe is not known. The attributable factor (13 and 7 % in females and males, respectively) of dietary cadmium to this effect on bone tissue is assumed to be the same in the different EU countries; there are no data indicating otherwise."*

Regarding the risk it is stated in the background document:

"The change in cadmium intake, due to the proposed restriction of cadmium in artists' paints, is estimated to generate a reduction in the number of fractures affecting women and men over 50 years of age, and in the number of women over 50 afflicted with breast cancer. The effects on fracture and breast cancer cases in the EU 27 from a full restriction on the use of cadmium based artists' paints will ***grow linearly from zero at the time of implementation to the following levels after 150 years [...]****:*

Table 2 (from the background document). Risk reduction capacity in terms of number of prevented fractures and breast cancer cases per year

Years from implementation	**Female fractures**	**Male fractures**	**Breast cancers**
	Health effect per year		
50	12	4	4
100	25	7	9
150	37	11	13
	Accumulated effects after implementation		
50	316	90	111
100	1251	358	440
150	2804	802	987

Although other toxic effects of cadmium have not been assessed in this report, it is expected that these will also decrease in a similar manner. Furthermore, the impact of the proposed restriction on the cadmium exposure via food will be higher among individuals eating locally grown potatoes and cereals, where sludge has been used as fertiliser (fertilising scenario C, section B.9.4). Individuals living in areas with conditions according to Scenario A are affected by cadmium in artists' paints at a 3 times higher level than in the average scenario and this situation may be relevant in some parts of EU."

It is noted, that EFSA is mentioning effects on bone fractures and breast cancer, but do not discuss them in details.

RAC has the following observations on these approaches:

1. It is aknowledged that since the EFSA opinion from 2009 several studies have been published on health effects of cadmium. This has strengthened the concern expressed by EFSA in their risk assessment, in particular for other endpoints than kidney toxicity e.g. cases of bone fractures and postmenopausal breast cancer.

2. A review on non-renal effects and risk assessment of environmental cadmium exposure was published earlier this year (Åkesson et al., 2014). The authors concluded that there is reason to challenge the basis of the existing health risk assessment for cadmium, from focus on kidney effects to bone effects and cancer.

   RAC also recognises that during the public consultation the ICdA questioned the scientific background of a relastionship between dietary Cd exposure and these effects.

3. Evaluation of these effects difficult due to e.g.:

   a. The time scale for 150 years when predicting diseases is very long.

      If seen in isolation such a long time frame might be justified, but since the effects in this particular case is based on predicting how sewage sludge will be deposited, it is too speculative. The deposition of sewage sludge is a very sensitive issue where different Member States currently have different approaches: some have targets for increasing the amount of deposited sewage sludge on agricultural land, where as others are going in the oppsosite direction. So even in a very short time frame of a couple of years, predicting the future use of sewage sludge is a difficult task.

      Additional aspects that depend on the chosen time frame are:

      - Better acceptance of Cd-free alternatives;
      - Technical improvements regarding the treatment of waste water and thus the environmental fate of Cd;
      - Different intake of cadmium in food due to change in eating habits or development of different food products;

      These aspects will have an influence on the anticipated risk reduction capacity but are at the moment not quantifiable as it is just not possible to predict how the progress in the above mentioned topics will develop and how they will interact.

   b. The anticipated impact of the proposed restriction are only limited to a very few actual cases when looked upon as factual numbers (less than a hundred out of the total population in the EU). It is recognised, that the DS has noted that the estimated number of cases for fractures and breast cancer are only two of the many different effects that can be caused by cadmium compounds. Fractures and breast cancer were chosen according to the DS because there are suitable data for these endpoints that make a quantitative assessment possible.

      The risk reduction capacity (number of avoided fractures and cases of breast cancer) is negligible compared to the total numbers of fractures and breast cancer in Europe. This is probably also true for all the other effects of cadmium exposure attributable to artist's paints.

      Even natural variability within a great population of several hundred millions will influence the numbers significantly given the small actual numbers. It is recognised that the DS have useddose-response relationships from studies on fractures and breast cancer for calculating number of cases and that they have used middlebound values for these relationships.

Conclusion 2:

The dossier submitter provided a thorough description of the possible effects – a description that is not challenged by RAC. However, the very small impact from the proposed restriction (estimated by the Dossier Submitter to be 48 bone fractures and 13 breast cancer incidents per year in 150 years) is considered to be of little or no relevance when compared to the conclusion of the EFSA opinion. Additionally, for the prediction of numbers of bone fractures and breast cancer, the uncertainties are not quantifiable but definitely high. A quantitative and reliable scientific evaluation of the risk reduction capacity is therefore not possible.

This conclusion should be seen in combination with the conclusion reagarding the low exposure from cadmium in artist paints and the conclusion related to the EFSA opinion.

Exposure ("From artist paints to soil and food")

As stated above, one of the basic premises for the proposal is that humans are exposed to cadmium from artist paints via food. During use and brush cleaning procedures, cadmium based artists' paint is released to the waste water. At the WWTP the cadmium pigments will mainly end up in the sewage sludge. Sludge can then be applied as fertiliser in agriculture. The cadmium compounds used in artists' paints will eventually dissolve in the soil, hence there is a potential for crop uptake and consequently exposure to humans via food.

If the cadmium input originating from artists' paints is removed, the average intake via food over 100 years is estimated to be reduced by 0.001 µg cadmium / day (compared to baseline), which is equivalent to 0.006% of total intake via food.

These premises, their quantification and uncertainties are discussed in the following.

From cadmium in artist paints to cadmiumin the environment (release factor)

A very crucial assumption for the whole proposal is the release "factor" of cadmium from cleaning of used artists brushes. In the Background Document this part can be found in chapter B.9.3 "User Scenario –Release from usage of artists' paints". Some highlights are given below:

In a study from 2000 different sources for the cadmium ending up in the sewage sludge were identified (Enskog 2000). Sales figures were used to quantify the amount of cadmium originating from artists' paints. It was further assumed that 5% of the paint will be released to waste water during usage mainly by cleaning of used brushes in a sink.

In 2006 the cadmium release from use of artists' paints in Stockholm was estimated based on the number of practising artists and art students in the area and the amount of cadmium colour each artists' might pour down the sink (Weiss 2006). According to the results 1.8, respectively 2.2 kg cadmium will be released to the WWTPs from artists' paints users in Stockholm annually which in 2005 corresponded to 7.2 to 8.8% of the total cadmium content in waste water of Stockholm.

Analyses performed on behalf of the City of Gothenburg indicated substantial release of cadmium from art schools which called upon action from the community (GöteborgsStad 2006). The municipal waste water company estimated that 10% of the cadmium reaching the treatment plant derived from artists' paints. A follow-up project demonstrated large flaws when handling the waste from cadmium paints. Cadmium pigments were released to the waste water when the artist's brushes and paint containers were washed after usage in the sink. None of the schools that permitted students to use cadmium colours could demonstrate a proper routine to avoid the paint to be released to the waste water, especially when it came to water based colours. During the second half of 2012, the Swedish Water & Waste water Association, SWWA (SWWA 2012) measured elevated concentrations of cadmium in the waste water at 6 out of 10 art schools despite earlier voluntary efforts by the schools to reduce the releases.

The CSRs relevant to this restriction (Lead Registrant 2013a, Lead Registrant 2013b) use the environmental release category (ERC) number 8c for consumer use of artists' paints. The default worst case release factor to waste water resulting from this use category is 1%. However, this is a default value used for different purposes and not specifically for artist paints (Description of ERC 8c: Indoor use of substances (non-processing aids) by the public at large or professional use, which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives, dyeing of textile fabrics). The dossier submitter disagrees with this release assessment since their consultation and literarture search have shown that the release is most likely higher.

According to the dossier submitter's summary, assessed literature studies show that it is difficult to estimate the amount of cadmium released during the use of paint. Simultaneously it is clear that current cleaning procedures can causecadmium release to the waste water. Despite voluntary efforts releases of cadmium-based paints occur. The dossier submitter's consultation gives the same indications, e.g. at art institutes in general there is insufficient information on how students should take care of their brushes and paint waste. It is however difficult to estimate the release amount since artists are a heterogeneous group. In the report a release to waste water of 5 % of the used paint is assumed. This is based on Enskog (2000). Also, this release estimation is not expected to have changed over the last decade and is therefore assumed to still be applicable. This assumption is rather an underestimation than an overestimation, especially when water based colours are used there might be a higher release to waste water (City of Gothenburg 2006). However, during literature search the dossier submitter has not found any other studies estimating the release of artists' paints to waste water and therefore a release of 5% of the used paint is used in the background document. During the public consultation a relevant number (approx. 150) of artists (teachers, professionals and amateurs) claimed especially that the assumption of a release factor of 5% is too conservative. Additonally, one producer of artists' paints organised independently a survey in order to contribute meaningful information to the public consultation. Amongst other issues information was gathered about how the the amount of paint is minimized going down the drain during cleanup (see below).

Reliability assessment of a 5% release and difference between oils and water based colours

In reaction to the criticism voiced during the public consultation and the discussions in ECHA the dossier submitter reassessed the reliability of a 5% release factor using an EU exposure model for washing out of a brush used to apply paint.1 This model was primarily developed for biocidal products and skin exposure but the DS has concluded that some parameters and estimates can also be applied for artists' paints and release to waste water. In this EU model it is assumed that after painting 1/8 of the volume of the brush is paint.

If one estimates the volume of a typical artist's paint brush and the volume used per painting session an average release can be calculated.

To get access to such information the DS consulted a supply store in Stockholm, Konstnärernascentralköp.2 The store is run by a group of professional artists and cooperates with over 50 suppliers and delivers artists' paint within Sweden and abroad. Artist's paint brushes come in a variety of shapes and sizes, with natural or synthetic hairs. According to Konstnärenascentralköp their best seller for acrylics is a set of three different brush sizes. These sizes are the most popular both for beginners and professional artists. The difference is that beginners buy cheaper products and professionals tend to purchase brushes of higher quality. For the reliability assessment the DS used the medium brush assuming that all of the brushes included in the set are used with the same frequency.3 The

[1]HEEG opinion on exposure model Primaryexposure scenario – washing out of a brushwhich has beenused to applypaint. Ispra, 07/07/2011

[2] Established in 1962, http://www.konstnarernas.se/omoss.html?submenu_id=-1

[3] Size of small brush: 1.1 x 0.5 x 0.2, large brush: 2.7 x 1.5 x 0.5 (cm)

average brush has a size of 2 x 1 x 0.5 cm, which corresponds to a volume of 1 ml. Using the EU model results in that 0.125 ml (1/8) paint will remain in the brush after painting.

According to consultation at the store 2 ml cadmium based paint (mainly acrylics) is used at each painting occasion. Even though this is assumed to be a realistic example, there are obviously differences amongst artists. Since cadmium based paints are expensive they are however not used in excess. This has been communicated through the public consultation. As indicated in the stakeholder consultation in section G in the BD, cadmium colours are denser and less paint is needed during use. A use of 2 ml paint provides a potential release of 6.3% (0.125ml/2 ml). RAC notes that the model for washing out of a brush used to apply paint (from Heeg 2011) is a worst case scenario assessment not specifically meant for artist painting or for deriving a release factor, but it is used in lack of better alternatives.

This average potential release of 6.3% only covers release from brushes. There are other routes for the paint (especially water based paint) to reach the waste water, e.g. cleaning of palettes and emptying cans in the sink.

On the other hand there are artists making efforts to avoid release of paint during usage. In a survey received during public consultation4 64% (based on 500 respondees out of the total of approximately 1000) of the EU respondents claim they take steps to minimise the amount paint released to the waste water:

- 39% responders to the survey stated they prevent all cadmium from going into the wastewater system. Methods specified included utilization of hazardous waste collection events or services; letting cleaning water evaporate and disposing of solids as solid waste or reusing residue in artwork; using waterless cleaning methods; and on-site disposal.
- 35% indicated that they do wash brushes in the sink, but are careful to first wipe or pre-clean (using solvent, or waterless cleaner) excess paint from the brushes, allow it to dry and then dispose of it in the trash or reuse it in artwork.
- 12% replied that they use disposable palettes, or that excess paint is allowed to dry on the palette, scraped off and disposed of in the trash.
- 8% considered their careful and sparing use of cadmium colors as waste minimization.
- 5% attempt to filter or decant wastewater prior to disposal.

This is important information even though a majority of artists taking minimising steps still cause some degree of release. Also, the survey reveals that there are a lot of artists not taking any measurements at all (36% of the EU respondents). 12% of the respondents use disposable palettes or dispose of excess paint in the trash. This suggests that an important release route might be via cleaning of palettes in the sink. Some artists have mentioned that the palettes with oil based paints can be used for several weeks without cleaning.The survey also indicates that specialised cleaning methods are complicated, for example less than 5% are attempting to use e.g. flocculation and filtering.

However, the validity of the survey cannot be evaluated by RAC at this point.

Comments received during public consultation state that there are important differences in how oil and water based paints are handled. Brushes used for oil based colours are for most part wiped with tissues and left in turpentine or solvent. Also excess of water based paint on the brush after usage is in some cases wiped off before cleaning. Therefore a lower release to waste water can be assumed for oil colours, even though release from oil based paint occurs to some extent according to consultation (section G in the BD) and comments received during public consultation. An alternative to using a 5% release for all cadmium based artists' paints would be to separate oils from water based colours and use a higher release rate for water based colours (6.3%) and a 1% release for oils (according to the

[4] by Golden Artist Colors, A total of 1518 survey responses were received from EU and outside EU

general default value presented by the lead registrant). This would however only include release from brushes whereas the 5% used in the proposal also includes release from e.g. washing of palettes.

Furthermore, a study by Risk & Policy Analysts Limited[5] (2000) uses a 5% release to waste water in its estimates. This report was prepared for the European Commission, DG Enterprise. The report argues that part of the paint is removed from the brush with e.g. a rag before rinsing in either soap/water or solvent. Moreover it is discussed that water based colours have a larger potential to disappear down the drain whilst oil colours are less likely to be released to the waste water. Based on consultation with stakeholder the report assumes a general release rate of 5% as a result of brush washing etc. during use of artists' paints.

The default release rate of 1% (coming from the ECHA guidance from 2012) used by the registrants is based on substances physically or chemically bounded into a matrix, whereas the subject in the proposal is release of cadmium from cleaning of brushes etc. The DS is of the opinion that according to their actual studies on release from artists' paints (described in the BD) the release is most likely higher, as also supported by their consultation with different stakeholder (see section G in the BD).

The DS summarises their conclusions as follows: "*To evaluate the reliability of the 5% release rate used in the dossier the DS has used an EU exposure model in combination with consultation. This resulted in a release of 6.3% from cleaning of brushes. The estimated 6.3% is mainly applicable for water based colours. Since oil colours in general have a lower release to waste water an average release for the whole group of artists' paints is most likely lower. On the other hand, there are other potential release routes when paint is used (e.g. washing of palettes) which suggests that 6.3%, which only reflects washing of brushes, might be an underestimation. Taking all this into account, the DS assesses that a 5% release considering all cadmium based colours is a realistic release scenario. This release rate is also assumed (based on consultation) in a RPA report prepared for the European Commission, DG Enterprise, which is described above (Risk & Policy Analysts Limited 2000)".*

RAC has the following observations:

- RAC considers the reliability assessment made by the DS to justify a release factor of 5% as a starting point. RAC also recognises that this factor is very diificult to verify. It is also recognised that the default value of 1% is meant for substances that are chemically or physically bound into a matrix.

  Here the issue is a release of cadmium from the cleaning of the brushes etc..This situation is very different from what is the basis for the default value of ERC 8c of 1%. Hence, the release factor of 5% is better supported than the default release factor of 1%.

  During public consultation a release factor of 5% has been challenged. This challenge was not quantified but only described. Therefore it is not possible to derive a different release factor on this basis.

  It is also not possible to evaluate whether or not the estimations from the art school in Stockholm are representative for other art schools in the EU.

[5]Risk & Policy Analysts Limited, 2000. *The risks to health and environment by cadmium used as a colouring agent or a stabiliser in polymers and for metal plating*. Final report prepared for the European Commission, DG Enterprise. Loddon, Norfolk. Available at: http://www.rpaltd.co.uk/documents/J316-Cadmium.pdf, accessed 25/06/2014.

- Use of a 1% release factor will result in a reduction to 1/5 of the calculated numbers (9-10 bone fractures and 2-3 cases of breast cancer per year).

- It is also unknown how much cadmium will be released over time from paintings. It is not likely that all paintings will last forever, even when they are painted in Europe using cadmium-containing paints. Finally the cadmium in those paintings (with the exemptions of a probably little fraction which is considered as cultural heritage or valuable art) will be treated during waste handling and will thus not end in waste water sewage treatment plants.

- RAC assumes that there is no release of cadmium based paints to the waste water from surplus paints. Surplus paints containing cadmium are assumed to be treated by painters as hazardous waste (legal requirement according to the European Waste Catalogue EWC 0801 11 - Commission Decision No. 2000/532/EC and this is also indicated in several responses to the public consultation.

Conclusion 3:

RAC considers the release factor of 5% to be better justified based on the reliability assessment made by the DS than the default value of 1 %. Therefore this figure will be used as the basis for the calculations of the effects recognising the uncertainty in this kind of calculations. However, it is recognised by RAC that the release factor of 5 % is not really a reliable figure and adds significantly to the uncertainties of this assessment.

Oil based vs water based artist paints

Another key aspect is whether or not there is a difference in the release of cadmium from water based paints versus oil based paints; is it right to say that the two different types of paints are cleaned in the same way or are painters cleaning the oil based paints in a way that will prevent release to the waste water?

With the purpose to estimate the amount paint released during use and cleaning the dossier submitter has been in contact with art schools and practising artists (for details see section G of the BD). How paint leftovers are handled and which cleaning procedure is used differs between artists depending on tradition, experience etc. Brushes used for oil based colours can be wiped with tissues and then left in turpentine or solvent. It is also common to wash the brushes and cans with soap under running water where cadmium compounds have the potential to be released. When water based paints are used most cleaning occurs under running water in the sink.

In an analysis on cadmium based artists' paints conducted by the Swedish Chemicals Agency 2013 (see Appendix 5 of the BD) the following concentrations of cadmium were found and are presented in the table below

If these are representative for the whole EU market is not discussedby the DS (15 of 20 samples are from the same supplier). RAC cannot conclude on this question.

In the calculations that are used by the DS, the variation within the same colour type is dealt with by using the average value of each colour type. The arithmetic mean is assumed to be a representative value since the geometric mean and the median give similar results.

The DS has also looked at he market shares of the different types of paints.

Table 3. Market share of different types of artists' paints and their cadmium content (revised table 16 from the BD)

Type of colour	% of EU market (based on value)	% of EU market Included sum of pastels & pencils and others (proportionally divided) In terms of quantity	Quantityon EU market Tonnes/year	Concentration of Cd in the paint	Cadmium Quantity Kg/year
Oil	17	14	5.3	15-50 %	1897
Acrylics	33	79	30.8	6-17 %	3710
Water colours	10	4	1.6	30-45 %	563
Gouache	4	3	1.3	Approx.15 %	187
Dry techniques	20			-	
Others	16			-	
Total	**100**	100	**39**	**-**	**6357**

Red: oil based

Orange: Water based

RAC has the following observations:

a) There are large differencies in the content of cadmium in the different paints, both within the individual types and between the different types of paints. No general picture can be drawn, but paints containing generally from 6% to 50% cadmium with the lowest general content in acrylics with 6%-17% in the examined paints.

b) The water based paints constitute the majority on the EU market both in terms of quantity of paints and quantity of cadmium. Water based paints seems to be the most relevant type of paint regarding the release to waste water.

c) Disposal of water-based and oil-based paints from brushes is different as described in the above chapter regarding the release factor. This is also described in many of the comments received in the public consultation. However, it is difficult to evaluate how many artists choose which cleaning method for brushes and the potential release to waste water. Neither is it possible to evaluate if professional and amateur painters treat the cleaning process differently. Oil paints are claimed to be used primarily by professionals, but this cannot be verified by available data.

d) Watercolour paints (aquarelles) are suspended in water and may be reasonably expected to be washed down the drain. Gouaches are less common and suspended in a natural organic binder. However, the largest overall usage by artists is of acrylics and while water based, these paints are designed to polymerise and dry hard in an hour or less, indicating a possibly particulate behaviour in sewers and WWTP. Oil paints are usually diluted before application in a linseed oil painting medium, i.e.

vegetable triglycerides and will form micelles in water; the oil medium polymerises only over weeks. These aspects might influence the fractions arriving at the WWTP. But this cannot be evaluated and quantified from any data presented in the background document or during public consultation

e) A differentiation in the restriction between the 2 types of paints has been proposed in the public consultation, where the restriction should only cover water based paints.

f) Another proposal was to only ban cadmium containing paints for the general public, so only professional painters would be allowed to buy and use the cadmium containing paints

Since it is not possible from the available data to evaluate whether or not these two suggestions have an influence on the exposure, these proposals are not considered further by RAC.

g) It is mentioned in the public consultation that the cost of these cadmium containing paints is significantly higher than the other types of paints. This gives uncertainty to the overall calculations on the total volumes and could perhaps be considered further by authorities.

Conclusion 4:

The cadmium content differs between the different types of artist paints and also within the individual types of paints. The acrylics have, according to the figures presented, the lowest content of cadmium (6-17%) and this category constitutes the majority (3.7 t out of 6.4 t) of the paints on the EU market when it comes to total cadmium volume. If only water-based artist paints would be restricted, then the effects would be estimated to be reduced by roughly 1/3.

It is not possible from the available data to evaluate whether or not a differention between sale to the general public or only to profesionals would have a significant impact on the exposure.

Release of cadmium from pigments

An important issue is the release of cadmium from pigments; does it differ from other substances, i.e. is cadmium more tightly bound to pigments than other cadmium containing substances and will it therefore not be bioavailable?

Cadmium adsorption in soil and by this its bioavailability is strongly controlled by soil pH and soil organic matter, but is also influenced by a range of soil constituents. Therefore the dossier submitter provided extensive information about the most relevant parameters.

One major basis of the risk assessment provided by the dossier submitter is a consultancy report prepared by Jon Petter Gustafsson (Professor in Soil and Groundwater Chemistry at the Department of Land and Water Resources Engineering, KTH Royal Institute of Technology in Stockholm, Sweden). RAC evaluated this report about available information in the scientific literature.

In his report (Annex III of the background document) Prof. Gustafsson demonstrated that cadmium sulphides and selenides in pigments are thermodynamically unstable in the surface horizon of agricultural soil (strictly speaking Gustaffson's argumentation is restricted to Swedish soils, from the background document it is not clear whether this is relevant for the whole of Europe). The presence of oxygen and trivalent iron will lead to gradual dissolution of these compounds. Sulphide-bound cadmium can persist in soils over a time scale of years only if there is an excess of sulphide–bound zinc. Additionally the

dissolution rate of cadmium-containing sulphides is dependent on the amount of crystalline zinc sulphide in contact with the cadmium, as zinc will be dissolved preferentially from a mixed cadmium zinc sulphide mineral. In the absence of crystalline zinc sulphide, cadmium will be dissolved completely after 1-3 years. The presence of crystalline zinc sulphide can extend the life span of cadmium sulphide to 1-2 decades; however, sewage sludge contains mostly amorphous zinc sulphide that will dissolve more quickly.

From the data assembled in this review it was concluded that cadmium pigments probably will dissolve completely in soils over a time-frame of years to decades. It is therefore likely that, within a time frame of a couple of years to several decades, cadmium from pigments has a similar solubility and bioavailability as an easily soluble cadmium salt such as cadmium chloride. However, this report does not substantiate its findings by experimental data for paints or pigments.

During public consultation the International Cadmium Association (ICdA) has confirmed the conclusions by Prof. Gustafsson that Cd in pigments will become bioavailable in the timespan of years. It has also been concluded that there is no data that oppose that Swedish soils are representative for the same types of soils throughout Europe.

The assumption of equal availability of cadmium from pigments in sludge as the entire soil cadmium is considered an overestimation in most cases. The reason for this is the so-called sludge protection hypothesis, probably caused by other micronutrients added via sludge that compete with cadmium for uptake. This means that the cadmium exposure in the sludge scenario is likely somewhat overestimated by that assumption. It is however unclear whether this effect will last for decades as this is anticipated by the dossier submitter as a relevant timeframe for the risk assessment.

Additionally, industry also criticizes that the dossier submitter did not use the mean soil pH of 5.8. The value used for the risk characterization (with pH 6.5, a value that increases the exposure in the average scenario) is considered representative for the 65th percentile of pH but not of the mean or median. As this is one of the most important parameters changing the overall cadmium mass balance industry asks for reflection on this aspect.

RAC has the following observations/questions:

a) The argumentation by Gustaffson's is restricted to Swedish soils. However ICdA has confirmed that Swedish soils are not different from other EU soils in general. RAC notes that UK and Irish soils might have a higher Cd content, but this has not been evaluated further

b) Industry has indicated that Cd in sewage sludge is less bioavailable (by about a factor of 2) that in soild alone and that should lead to lower bioavailaibility of cadmium. However, for the chosen timeframe this 'sludge protection' will not prevent that cadmium from becoming bioavailable.

c) Cadmium can be found in crops, so it is clearly bioavailable. This is demonstrated in the EFSA opinions as well as the background document. It is also shown that different crops contains different levels of cadmium and therefore the uptake of cadmium by the population is depending upon the diet, but this is not looked into further by RAC as the overall conclusion is that is out of the scope for RAC and as EFSA has already made their conclusions on this.

Conclusion 5:

In summary and taking into account the information described above, it is assumed in this assessment that cadmium in soil, originating from pigments, in the long-term will be equally available to plants as cadmium from other sources.

Cadmium from artist paints in relation to other sources

Based on the conclusions above that cadmium released from artist paints will (eventually) be bioavailable and thus can be found in crops it is important to look at the contribution from this source in relation to other sources of cadmium.

The figures from the background document are very clear when taking into account that the background document operates with a loss to the sewage systems of 5% of the total amount of artist paints.

It is estimated in the BD that 0.32 tonnes cadmium from use of artists' paints is released to the waste water each year in Europe based on a 5% release factor. A majority will end up in the sewage sludge at the municipal waste water treatment plant (MWWTP). However not all households are connected to such a treatment.

As a result of stricter waste water treatment demands this suggests that the percentage presented in the EC implementation report might be somewhat higher today. However, a connection rate to WWT of 82% as stated in the report (EC 2013a) is assumed for EU and used in calculations in the background document.[6]

Using the median value of 1.4 mg Cd/kg dry substance (Table 18 in the BD) and estimates of sludge production (11 811 000 tonnes, table 21 in the BD) give a total of **16.5 tonnes** cadmiumin EU produced sewage sludge.[7] RAC has calculated that **0.11 tonnes** originate from artists' paints which is **0.7%**[8] of the total cadmium in EU produced sludge.

Other sources

The figures are taken from section B.9.3, B.9.4 and B.9.5 in the background document where the different scenarios are described.

The cadmium found in agricultural land originates mainlyfrom fertilizers and sewage sludge from WWTP used as fertilizer (and sometimes soil improvement). The contribution from artist paints is very small when looking at absolute and relative numbers: The total amount of cadmium applied on agricultural land from sludge in the EU is estimated to be 7.4 tonnes cadmium annually of which only 0.11 tonnes (also estimated, see page 19) originates from artist paints equivalent to less than 1% of cadmium from sludge.

However, when looking at the total amount as given in table 28 of the background document (see below), then the percentage is an order of magnitude lower (0.2%) depending on which scenario is used (see Annex 1 for a description of the scenarios).

[6]The DS assumes that the produced sludge is from a plant with secondary treatment. A majority of the EU Member States gather their waste waters in collecting systems with an average compliance rate of 94%. However, there are Member States where there is only partial or in some cases no sewage collection (EC 2013a)

[7] 1.4 g Cd/tonne ds x 11 811 000 tonnes ds = 16.5 x 10^6 g Cd = 16.5 tonnes Cd

[8](0.11/16.5) * 100

Table 4 (Table 28 from the background document, revised). Sources of cadmium in soil.

Source	**Cd (t/y) EU total**	Scenario A 30 kg P ha^{-1} y^{-1} Cd (g ha^{-1} y^{-1})	Scenario B Low application rate Cd (g ha^{-1} y^{-1})	Scenario C Only fertilising with sludge Cd (g ha^{-1} y^{-1})
Sludge	**7.4**	0.2	0.07	10.5
Artist paints	**0.11**			
Deposition from atmosphere	**24 (23.7)**	0.23	0.23	0.23
Mineral fertiliser	**85 (84.6)**	2.2	0.82	-
Manure	**1-2**	-	0.01	-
Lime	**-**	0.09	0.09	0.09

RAC has the following observations:

a) The contribution of cadmium from artist paints to soil and thereby crops is negligible compared to other sources (0,086% [9]).

b) The importance of this source is therefore questionnaible. On the other hand it contributes to the general pool of cadmium that can be taken up by crops.

c) Other sources like e.g. mineral fertiliser are clearly more important.

d) During the public consultation member states, organisations and individuals pointed frequently at the fact that other sources like e.g. cadmium in fertilisers are far more important.

Conclusion 6:

The contribution of cadmium from artist paints to soil and thereby crops is negligible compared to other sources. This is of course true for many uses/sources as a single use will often be small on a relative scale.

However, also this source contributes to the general pool of cadmium that can be taken up by crops. EFSA concluded that the cadmium contribution from food intake is too high for certain parts of the population.

Alternatives

The product assortment of two online stores (www.winsornewton.com and www.sennelier.fr) was analyzed by the dossier submitter for cadmium free paints. In these stores 24 unique pigments were found in products that were cadmium free but where the names of the products contained the word cadmium.

[9] [0,1 / (7.2+23.7+84.6+1)] * 100

RAC notes the Dossier Submitter has looked at the hazards to human health and the environment of a number of the non-cadmium alternative paints/pigments, which in their assessment are less hazardous than the substanes subject to the restriction.

A limited number (< 20 out of 666) of the contributions in the public consultation state that cadmium-free alternatives are available and that these are feasible from an artist's point of view. The vast majority of the contributions deny the availability of suitable alternatives.

Since the question of suitable alternatives is an aesthetic and technical issue RAC did not evaluate the suitability of such alternatives further, particularly as there was no request from SEAC to do so.

RAC observes that the use of cadmium in the names of the cadmium free products could have had an influence on at least some of the many submissions during the public consultation strongly arguing for the continued use of cadmium, depending on in which types of shops the paints are sold. If people think that the colours contain cadmium then they might respond to this, even though the colours are cadmium-free. On the other hand, it could be argued that painters are very keen on how the paints perform and might have a personal preference for a very specific tone of the color where others don't notice the difference or have another preference.

Conclusion 7:

The question of suitable alternatives, including their hazard, has not been evaluated by RAC.

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

The main reason for acting on a Union-wide-basis would be the serious health hazards associated to cadmium and its compounds and the statement from the EFSA. This use of cadmium and its compounds is not included in the current restriction in REACH Annex XVII, Entry 23.

A Union-wide restriction would thus be the best way of ensuring a "level playing field" among both EU producers and importers of artists'paints. A Union-wide restriction would also be easy to communicate to the suppliers outside the EU.

The demonstrated effects are an EU wide issue not related to any regional differences except for the use of WWTP sludge as a fertiliser etc., that could be different now and in the future between individual member states.

Conclusion 8:

As RAC is of the opinion that the proposed restriction is not the most appropriate measure to address the negligible risk, then consideration of whether action is required on an EU-wide basis is not relevant. However, for several reasons (e.g. time frame of 150 years, ongoing discussions about the use of sludge in the individual member states, statistically insignificant contribution to the number cases of breast cancer and fractures) it is unclear whether this restriction proposal would have the same impact all over Europe.

JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

It is clear that there are several sources of cadmium to the soil and thereby to crops and food intake.

The justification for the restriction relies on assumptions that cadmium from artist paints will enter the sewage system and thereby ending in sludge that is spread to soil. The contribution from artist paints is however negligible compared to other sources, but if it is deemed appropriate to do something about this source, a restriction would be the most efficient risk management measure in reducing cadmium from artist paints.

The proposed exemption for restoration and maintenance of works of art and historic buildings and their interior will reduce the effect; the argumentation for the exemption is a socio-economic issue and is therefore referred to SEAC.

Other measures have been proposed by the dossier submitter.

The dossier submitter has rejected inclusion in the authorisation list primarily because of lack of classification of the cadmium containing substances that are used in the pigments, and therefore they do not fulfil the criteria as such.

A voluntary agreement is also discussed by the dossier submitter and dismissed as being non-efficient primarily due to lack of enforcement mechanisms. Also risk of free-riders could be mentioned.

Economic policy instruments have been discussed, but the efficiency of such an instrument is dealt with by SEAC.

Stricter limit values in the sewage sludge directive are also discussed by the dossier submitter. Since the most important source to cadmium in the soil is use of fertiliser, a reduction of this source will of course be the most efficient in order to reduce uptake of cadmium. However, since the proposal is about cadmium in artist paints, this option is out of scope for an evaluation by RAC, even though it is recognised that this would be the most efficient way of reducing cadmium in soils.

Labelling has not been discussed as a risk management measure in the proposal. However during public consultation several contributions pointed out that a clear labelling could be an effective and less controversial measure. RAC notices that some contributions in the public consultation mention that at least some of the cadmium containing paints are labelled already, but RAC cannot judge if this is true for all paints. A distinct warning label could raise awareness among artist painters so they would clean brushes and palettes in an environmentally better way, but it is not possible say anything about the effectiveness.

Conclusion 9:

In terms of its effectiveness in reducing the risks from cadmium in artists paints alone, RAC is of the opinion that the proposed restriction is not the most appropriate EU wide measure to address the negligible level of risk but if it was deemed appropriate to do something about this small contribution to the overall input from cadmium, RAC considers the proposed restriction would be very efficient.

Effectiveness in reducing the identified risks

The contribution to reducing the impact of the identified risk is negligible as described

above. However, as stated, EFSA in 2009 expressed concern that the margin between the average weekly intake of cadmium from food by the general population and the health-based guidance values is too small. EFSA therefore suggest that exposure to cadmium at population level should be reduced (EFSA 2009).

The dossier submitter has modelled a scenario where effects on bone fractures and breast cancers have been calculated on a very long time scale in order to show the full effect of the contribution from artist paints.

Practicality, including enforceability

A ban on placing on the market of cadmium based artists' paints and pigments would require that producers and distributors have to be controlled to a certain extend defined by the member states. The required control of producers, importers, and distributors, is in line with regular monitoring procedures and shouldn't entail any specific challenges.

An exemption from the ban would however require additional enforcement to make sure that the selling of the products is justified by the exemption.

RAC agrees that the proposal would be practical to implement. The scope is clear even though the exemptions might create some difficulties when interpreted by different member states.

RAC has taken into account the FORUM advice.

Monitorability

The dossier submitter states that the monitoring of the restriction for cadmium and its compounds in artists' paints would primarily be done through enforcement. Additional monitoring can be exercised, e.g. through measuring cadmium levels in waste water from artist schools or workshops.

The number, extent and type of exemptions allowed by the Member States can be monitored by ECHA by requiring the Member States to document the exemptions in a common database.

RAC suggests that the most direct way of assessing compliance will be random sampling of articles by companies and authorities; although the use of contractual obligations is also an option for companies. A range of paints are already subject to analysis for cadmium due to existing legislation.

Conclusion 10:

The proposed restriction by the Dossier Submitter is monitorable, when seen from the point of view that enforcement can address whether or not stakeholders are complying with the proposed measure.

However, the numbers are so small that it will not be possible to monitor any effects of the restriction in the population. A decrease of 48 cases/year of bone fractures out of a population of several hundred million people would be impossible to monitor.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions.

Basis for the opinion of RAC

Considering the information in the Background document and the information submitted in the public consultation RAC does not consider the proposed restriction to be the most appropriate EU wide measure to address the negligible level of risk in terms of its effectiveness in reducing the risks from cadmium in artists paints.

References not included in the Background Document

Åkesson, A et al.: Non-renal Effects and the Risk Assessment of Environmental Cadmium Exposure. Environmental Health Perspectives, volume 122, no 5, 2014.

ANNEX 1

This section is taken from the BD and explains the different scenarios used in Table 4 on page 19 in the opinion.

In this report three fertilising scenarios are discussed and used in calculations in the human exposure via food assessment (section B.9.7).

A) Application of 30 kg P ha-1 year-1 (mineral as well as sludge fertilisers) according to realistic worst case, high input – low output scenario from the EU Risk Assessment Report (ECB 2007)

B) Average- A low application scenario where all sludge use in agriculture is spread over all arable land in EU together with other fertilisers

C) A realistic local worst case scenario where it is assumed that all fertilising of potatoes is performed with sewage sludge

As described in section B.4 it is in this dossier assumed that cadmium in soil, originating from artists' paints pigments, over time will be equally available to plants as cadmium from other sources. It is further expected that there is no difference in cadmium availability in sludge amended soils compared to native soils.

For *scenario A* an input of 30 kg P ha-1 year-1 is used. This is based on estimations from the EU RAR (ECB 2007). This scenariorepresents farming systems with high input, which according to the EU RAR may be found in e.g. wheat and corn rotations. Phosphorus applications in these systems are usually 30 kg P ha^{-1}. It is in this dossier assumed that the 30 kg P consists of both sludge and mineral fertilisers in the same relative amount as is used in the whole EU. According to the calculations in section B.9.3 approximately 0.12 million tonnes P, originating from sludge is annually used in the agriculture. Estimations above show that around 1 million tonnes P is applied by mineral fertilisers. If using this relation between used sludge and mineral fertilisers in scenario A, 11% will come from sludge and 89% from mineral fertilisers[10]. This gives a cadmium input with sludge and mineral fertilisers of 0.2 and 2.2 g ha-1 year-1 respectively[11].

Scenario B is the only scenario that can be applied on the whole EU population and therefore used to estimate the general risk for EU. However, this scenario is based on diluted data since all fertilisers are distributed evenly over all arable land. In addition to sludge with an input of 0.07 g Cd ha^{-1} $year^{-1}$[12] and mineral fertilisers with an input of 0.82 gha-1 year-1, manure contributes with 0.01 gha-1 year-1 according to calculations above.

Scenario C is a worst case local scenariowherewe assume that only sludge is used for fertilising in a crops rotation system. TheEuropean Commission report (Milieu 2010) mentioned above states that the limiting factor for sludge application is normally the maximum permissible supplement of total nitrogen (N_{tot}) which for most uses is 250 kg N ha^{-1} y^{-1}. The limit is set out in the Nitrates Directive 91/676/EEC and will be reduced to 175 kg N ha^{-1} y^{-1}in vulnerable zones. Under certainconditions it may also be allowed to apply 500 kg N ha^{-1}every second year if the nitrogenavailability of the fertiliser is low (which is possible for dewatered sludge). However, sewage sludge is a phosphorus rich fertiliser in respect to the P/N ratio related to the P/N demands of crops. This will result in an excess of P if the N demands of crops are met. Milieu (2010) emphasises that if the application rate of sludge is limited by P requirements of the crop it would have consequences for the operational capacity of using sludge in the agriculture since the application rate would have to be reduced. Also other studies show that N requirements of crop appear to be the

[10] 0.12/(0.12+1) and 1/(0.12+1)
[11] 11% x 30 kg P ha^{-1} x 60.5 mg Cd P^{-1} (Table 19) + 89% x 30 kg P ha^{-1} x 83 mg Cd P^{-1}
[12] 7.4 tonnes Cd (see section B.9.3.2.3)/102 961 800 ha

limiting factor for the sludge application rate due to P fixation by components in the soil(Rappaport et al 1987). According to Milieu (2010) the application rate of sludge is often 5-10 tonnes ds/ha. This gives an estimated average rate of 7.5 tonnes ds/ha[13]. Using the cadmium concentration of 1.4 mg/kg ds (Table 19) gives a load of **10.5 g Cd ha^{-1} y^{-1}** which is used in the human exposure via food assessment. However, in scenario C it is assumed that only potatoes are grown using sludge. Other vegetables and cereals are expected to be cultivated according to the average scenario.

For all three scenarios the annual deposition and lime are accounted for.

Table ~~Table 28~~ presents the estimations that will be used for further calculations in the human exposure via food assessment (section B.9.7).

[13] (5+10)/2

ATTACHMENT 2

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Cadmium and its compounds in Artist's Paints

Draft

26 November 2014

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(Draft)

27 November 2014

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**CADMIUM AND ITS COMPOUNDS (in Artist Paints)**
EC No.:	231-152-8 (Cadmium)
CAS No.:	7440-43-9 (Cadmium)

This document presents the opinions adopted by RAC and SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed grounds for the opinions.

PROCESS FOR ADOPTION OF THE OPINION

Sweden has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at **http://echa.europa.eu/web/guest/restrictions-under-consideration** on **19 March 2014**. Interested parties were invited to submit comments and contributions by **19 September 2014**.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on 26 November 2014.

The draft opinion takes into account the comments of and contributions from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published at **http://echa.europa.eu/web/guest/restrictions-under-consideration** on **10 December 2014**. Interested parties were invited to submit comments on the draft opinion by **8 February 2015**.

OPINION

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. Taking into account RAC's conclusions that the proposed restriction is not justified because the restriction under REACH is not considered to be the most appropriate EU wide measure to address the identified negligible risks in terms of its effectiveness in reducing the risks, SEAC considers that the proposed restriction is not the most appropriate EU wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs.

JUSTIFICATION FOR THE OPINION OF SEAC

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

SEAC agrees with the dossier submitter that the annual intake of Cd to agricultural soil is 120 tons (see Table 27 in the background document, sum of 118.4 t/a reduced to 2 significant digits). The largest intake fraction is from mineral fertilizer (72%), followed by atmospheric deposition (20%) and sewage sludge (6%). The dossier submitter estimated that from the Cd content in artists' paints sold in Europe 5 % of the cadmium is released to waste water by cleaning brushes at the sink (release factor), 4.1% are transferred to a waste water treatment plant (average connection rate to WWTP 82%) and 1.7 % are spread on agricultural land (sewage sludge utilization rate 40%), in terms of mass this would mean 6400 kg Cd in artists' paints, 320 kg Cd released to waste water, 260 kg Cd reaching WWTP and 110 kg Cd ending on agricultural land. In Tables 19-21 of the background document it is shown that Cd containing sewage sludge is applied in all European countries to various extents. If Cd from artists' paints was a significant source of Cd in sewage sludge, action on EU wide basis would be justified to ensure a level playing field among both EU producers and importers of artists' paints. A Union-wide restriction would also be easy to communicate to the suppliers outside the EU.

A prediction of the Cd intake to agricultural soil influencing the projected health benefits is highly speculative for such a long time frame. RAC concluded for the prediction of numbers of bone fractures and breast cancer, the uncertainties are not quantifiable but definitely high. A quantitative and reliable scientific evaluation of the risk reduction capacity is therefore not possible. The dossier submitter estimates that the proposed restriction will lead to a reduction of the Cadmium concentration in agricultural soil of 0.011% in addition to a reduction of 1.6% occurring as a result of the Cd fluxes to soil (input and output balance) over a period of 100 years. However, a recent paper on the future trends in soil Cd concentration predicts a decrease of 15% rather than 1.6% in 100 years (Six and Smolders, 2014). This underlines the uncertainty involved and casts doubt on the significance of the estimates made by the dossier submitter, such as those assumptions discussed in the following paragraph.

A very crucial presumption for the whole dossier is the release factor of cadmium from cleaning of the brushes. In the public consultation, numerous comments stated that artist's paints users handle paints economically and clean brushes with e.g. waste paper resulting in a transfer to solid waste management rather than to the waste water cycle. SEAC considers that the release factor of 5% used by the Dossier Submitter is uncertain. It is accepted that the usage of Cd containing artists' paints may result in emissions to the waste water. However, the value of 1% from the Chemical Safety Reports from the Lead registrants could also be a correct assumption, as long as no measurements on the release exist.

The consumer surplus arising from using Cd containing artists' paints is calculated in a highly subjective manner. The dossier submitter assumes that the maximum loss in consumer surplus (i.e. all users find the alternatives to be of no use at all) was 3.4 million EUR per year (i.e. 50% of the consumer expenditure). For the estimates in the dossier it was further assumed that between 10% and 20% of the estimated extreme value is lost in reality (i.e. 0.34 – 0.69 million EUR/a). SEAC notes the DS does not present any evidence that the actual consumer surplus is in reality approaching this value. A quantification of consumer surplus from using Cd containing paints is hardly achievable because the slope of the demand curve is not known (see section F.2 in the background document).

It should also be noted that these paints have mainly an aesthetic function. Most public consultation comments received on this issue stated that alternatives are often regarded as inadequate. These statements are supported by comparative measurements of light

fastness, opacity and tinting strength of artists' paints containing Cd and alternatives presented in the comments of the International Cd Association.

JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Effectiveness in reducing the identified risks, proportionality to the risks

Overall SEAC conclusion

As stated above, RAC have concluded that the very small impact from the proposed restriction (estimated by the Dossier Submitter to be 48 bone fractures and 13 breast cancer incidents per year in 150 years) is considered to be of little or no relevance when compared to the conclusion of the EFSA opinion. Additionally, the uncertainties for the prediction of numbers of bone fractures and breast cancer are not quantifiable but definitely high. A quantitative and reliable evaluation of the risk reduction capacity is therefore not possible.

Building on the RAC opinion, the opinion of SEAC is that based on the information given in the Background Document and obtained during the Public Consultation, a restriction of Cadmium in artists' paint would be disproportionate.

Costs and benefits

This opinion is based on an assessment of the estimates from the dossier submitter, who state that the projected benefits from the restriction[1] could outweigh the costs[2] after either 19 years[3] or only after 115 years[4] after implementation of the restriction. However, if the release factor of 1% is taken into account then the benefits from the restriction could outweigh the costs after 75 years[5] or would not reach break-even in the proposed time frame of 150 years[6].

There are large uncertainties in costs (such as loss in consumer surplus (see above)) and in benefits.

Benefits were calculated with two different approaches:

1.) from benefits from avoiding socio-economic costs from fractures and breast cancer cases (break-even of cost and benefits occurs after 115 years (20 % loss of consumer surplus, growth over time)), and
2.) from benefits from avoiding socio-economic costs from fractures and the willingness to pay (WTP) to avoid breast cancer cases (break-even of cost and benefits occurs after 46 years)

    In approach, 2 a value for WTP of 396.000 EUR was used (Alberini and Ščasný, forthcoming).

1 Monetised impacts resulting from fewer bone fracture and breast cancer cases

2 Reduction in consumer surplus, administrative costs for proposed exemption and cost for discarded products

3 Table 58 in the BD, benefits calculated according to alt. 2, costs according to assumption b

4 Table 58 in the BD, benefits calculated according to alt. 1, costs according to assumption c

5 Table 58 in the BD alt. 2, assumption b – 1% release factor

6 Table 58 in the BD alt. 2, assumption c – 1% release factor

SEAC acknowledges that even small reductions of cadmium from any source and anywhere in the food chain may result in reductions in health impacts. However, SEAC considers that taking into account the uncertainties in the restriction dossier, it does not present sufficient scientific argumentation regarding the option for 150 years of full effect of the restriction. The small reductions, especially over the quoted time period, appear to be statistically of very low impact (particularly in terms of public health impact) and therefore any measurable benefits from the proposed action are questionable.

Therefore SEAC are of the opinion that the proportionality of the proposed restriction is questionable taking into account the scale of uncertainty regarding the impact pathway disease burden estimation of the number of cases.

Availability and technical feasibility of alternatives

Alternatives to Cd-containing artists' paints are available. However, during public consultation it has been brought up by industry and by a large number of comments (341 out of 666) by artists using the paints that alternatives to artists' paints containing Cd do not provide the same technical specifications as Cd pigments e.g. regarding lightfastness, opacity and tinting strength (at least more paint has to be put on the canvas to achieve similar results). These parameters are mainly associated with aesthetic aspects of the paintings and therefore cannot be monetized easily. In addition to the familiar concept of technical feasibility of alternatives, the aesthetic aspects of the paints needs to be fully taken into account due to their role in painting/production of art. There is a strong assertion from public consultation that the alternatives are not of equal value.

In addition to the uncertainty around the proportionality of the proposed measure, there are a number of alternative risk management options for managing the risk.

In the restriction report other risk management options than restriction are discussed. One of these alternative options is a stricter limit for Cd in the sewage sludge directive (86/278/EEC) than that of 20-40 mg Cd/kg. For sewage sludge a decrease of the average Cd concentration (1.4 mg Cd/kg) in the order of 0.021 mg/kg (or 0.004 mg/kg for the lower release factor) would have the same effect as the proposed restriction and is likely to be in the same range of costs (see BD Section E.1.3, paragraph on Stricter limit in sewage sludge directive). Depending on the distribution pattern of Cd concentrations in sewage sludge this could be achieved by the exclusion of only a small mass of highly contaminated sewage sludge, e.g. by voluntary quality assurance measures. The same is valid for mineral fertilizers (see below, not discussed in the dossier).

Although not assessed in the restriction report, there are two other possibilities for risk management.

The amount of Cd originating from artists' paints on agricultural land is according the restriction dossier 110 kg per annum within 120 tons in totals (see background document, Table 27) and only 22 kg with the lower release factor of 1%. A decrease of the average Cd concentration in mineral fertilizers (7.4 mg Cd/kg) in the order of 0.0096 mg/kg (or even 0.0019 mg/kg for the lower release factor) would have the same effect as the proposed restriction. Cd concentrations in mineral fertilizers range from 0.7 to 42 mg/kg (Nziguheba and Smolders, 2008) thus such a minute reduction could be achieved by excluding a small mass of products with high concentrations.

Public consultation has also revealed that some users of artists' paints containing Cd are not aware of the potential hazards to environment and human health. An alternative risk management option would therefore be labeling the paint tubes with appropriate warnings and instructions on disposal.

In addition, a Cadmium tax could be introduced as previously practiced in Sweden for fertilisers with more than 5 mg Cd per kg P (Oosterhuis et al., 2000). A national Cd tax could also help to exclude sewage sludge with high Cd concentrations from agricultural application (see section E.1.3 in the background document, paragraph on Economic policy instruments). It is obvious that the projected reduction by the proposed restriction is so small that it can be achieved also by alternative measures with the same range of costs. In any case the estimated emission of Cadmium to agricultural soil of the proposed restriction is hardly observable. Likewise is the impact on human health hardly observable. According to the restriction dossier the health impacts is growing linearly within 150 years from zero to 13 fewer cases of breast cancer among 374,200 cases, 37 fewer fractures for females among 4,600,000 cases, 11 among 2,400,000 for males (release factor 5%). For the release factor of 1% the data are even lower by a factor of 5.

Given the uncertainties in the complex exposure scenario, the considerable Cd input from other sources, and given the economic, societal and technological developments over next 100 years, which are of course not predictable and therefore not included in the restriction dossier, SEAC considers that a restriction of Cd in artists' paints is not the most appropriate and effective measure to reduce the Cd intake of consumers and the associated health risks. In addition, other risk management measures with the same range of costs could be used to achieve greater risk reduction but the detailed information to fully assess these alternatives are not readily available to SEAC.

Practicality, incl. enforceability

SEAC is of the opinion that the proposed exemption for restoration and maintenance of historical pieces of art from the ban would require additional enforcement to make sure that the selling of the products is justified by the exemption. However, as this discretion of the MS to decide on such an exemption, MS would have to take also enforceability into consideration.

However, SEAC considers that based on available information (Background Document, Public Consultation) no further action concerning REACH restrictions is to be taken to manage the possible risks arising from Cd containing artists' paints the assessment of the practicality of the different identified RMOs is no longer relevant.

However, public consultation revealed that enforceability of a ban might be difficult. Numerous commentators announced that they will order artists' paints outside EU via Internet (e.g. from the US).

Monitorability

SEAC agrees with the dossier submitter that the monitoring of the restriction for cadmium and its compounds in artists' paints would primarily be done through enforcement. Additional monitoring could not be exercised, e.g. through measuring cadmium levels in waste water from artist schools or artist's workshops.

SEAC considers that based on available information (Background Document, Public Consultation) no further action concerning REACH restrictions is to be taken to manage the risks arising from Cd containing artists' paints the assessment of the monitorability of the different identified RMOs is no longer relevant.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions.

Basis for the opinion of SEAC

SEAC has no basis to support the proposed restriction as proposed in the Annex XV restriction dossier submitted by Sweden.

References not included in the BD

Alberini, A. and Ščasný, M. (forthcoming). Stated-preference study to examine the economic value of benefits of avoiding selected adverse human health outcomes due to exposure to chemicals in the European Union, Part III: Carcinogens. Environment Center, Charles University Prague (CZ), FD7. Final Report, Service contract for the European Chemicals Agency No. ECHA/2011/123.

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Nziguheba, G. and Smolders, E. (2008). Inputs of trace elements in agricultural soils via phosphate fertilizers in European countries. Science of The Total Environment 390(1), 53-57.

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