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**Attention: Docket Number H054a**

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**Comments of**

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# On the Proposed Rule for Occupational Exposure to Hexavalent Chromium

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**Introduction:**

Many of the concerns that Elementis Chromium has about this rule have been submitted to the docket for this rulemaking previously. This submission is intended to review some of the aspects that we do not believe that OSHA has properly considered and to respond to some of the issues raised by OSHA in the preamble of the proposed rule.

Elementis Chromium is the only U.S. manufacturer of the basic hexavalent chromium chemicals, sodium dichromate and chromic acid. It also manufactures the largest volume of these chemicals worldwide. Consequently we believe that our experience in handling Cr(VI) chemicals is significant although, our industry has relatively few workers.

These comments will consist of two parts. The first will be responses to selected issues proposed by OSHA in the preamble of the proposed rule. In the second part will be additional comments that we believe to be relevant to OSHA's consideration of this rule.

We are especially concerned about the very low proposed PEL of 1 $\mu g/m^3$. We do not believe that the available toxicological data or worker exposure experience justifies a value this low for the many industries and types of exposures covered by the rule. Also, we do not believe that this value is economically achievable by many facilities or technically achievable at the confidence level most facility managers expect. Recent advances in understanding of the effectiveness of various methods of sampling for air contaminants in the workplace will be discussed. This information raises significant doubt as to the usefulness of the exposure data obtained from the site visits conducted by OSHA and its contractors. Consequently, OSHA needs to completely reexamine the economic and technical feasibility analyses performed for this rule.

**Responses to Section II. Issues:**

5. **OSHA has relied upon a linear relative risk model and cumulative Cr(VI) exposure for estimating the lifetime occupational lung cancer risk among Cr(VI)-exposed workers. In particular, OSHA has made a preliminary determination that a threshold model is not appropriate for estimating the lung cancer risk associated with Cr(VI). However, there is some evidence that pathways (*e.g.*, extracellular reduction, DNA repair, cell apoptosis, etc.) may exist within the lung that protect against Cr(VI)-induced respiratory carcinogenesis, and may potentially introduce non-linearities into the Cr(VI) exposure-cancer response. Is there convincing scientific evidence of a non-linear exposure-response relationship in the range of occupational exposures of interest to OSHA? If so, are there sufficient data to define a non-linear approach that would provide more reliable predictions of risk than the linear relative risk model used by OSHA?**

We believe that use of a linear relative risk model can lead to a serious overprediction in estimated risks especially when it is based on effects at very high exposure levels. As OSHA notes on page 59344 of the Proposed Rule "OSHA believes the results of the Steinhoff *et al.* (Ex. 11-7) study show that the rate at which Cr(VI) is administered may be an important determinant for carcinogenic potency and thus useful for hazard identification purposes." Earlier OSHA described the results of this study. On page 59343 of the Proposed Rule a summary of the results from exposure by intratracheal instillation of a solution containing sodium dichromate is presented.

> *The total cumulative dose for the lowest treatment group of animals treated once per week was the same as the lowest treatment group treated five times per week. Similarly, the medium and high dose groups treated once per week had total doses equivalent to the medium and high dose animals treated five times per week, respectively. No increased incidence of lung tumors was observed in the animals dosed five times weekly. However, in the animals dosed once per week, tumor incidences were 0/80 in the control animals, 0/80 in 0.05 mg/kg exposure group, 1/80 in 0.25 mg/kg exposure group and 14/80 in 1.25 mg/kg exposure group (p <0.01).*

We agree with OSHA that these results do indicate that the rate of Cr(VI) exposure is important. The intratrachael instillation technique delivered Cr(VI) directly to the lung tissue without any filtering by the nose etc. so it was a true dose not just an exposure level. Also it was administered very quickly so that it was like a short-term high exposure. The sodium dichromate results clearly showed occurrence of lung tumors at the 1.25 mg/kg dose level given once a week. Making the conversion from sodium dichromate dihydrate to Cr(VI) this calculates to be 0.4375 mg/Kg. The test group that received the same weekly dose spread over five days received a maximum daily dose of 0.0875 mg/Kg. Based on this study, it appears that by lowering the highest repetitive daily dose by a factor of five, the risk was lowered by at least a factor of five even though the cumulative lifetime dose remained constant.

This study should be considered an extreme exposure for several reasons. The dose was applied directly to the lungs of the animals. The filtering mechanisms that will filter out most of the larger particles associated with a real world exposure and that might be part of the measurement when sampling for exposure levels, were not involved. All of the Cr(VI) was dissolved and therefore potentially bioavailable. Since cancer from Cr(VI) exposure appears to be due to action directly on exposed lung cells, the differences in respiration rate between rat and man should not be involved. This was clearly a lifetime exposure study with exposures continued until death of the animal or at the end of 30 months. (The Sprague Dawley rats used in this study typically live about 24 months. Repetitive exposure over an extended period leading to irritation effects may also be important. In the Steinhoff publication it says that after about the 415 day of the trial most of the rats receiving the highest dose showed signs of labored breathing for a short period following the dosing. The 415 day period is over half the expected lifetime of these animals. The publication also reported that the appearance of inflammatory lesions was much greater in the 1 x 1.25 mg/kg group than the 5 x 0.25 mg/kg group although the weekly dose was the same.

At this point it is interesting to compare the Steinhoff animal test data to that from the inhalation study by Glaser *et al.* (Exs. 10-10; 10-11). The Glaser study was an 18 month exposure using Wistar rats so it occurred over an appreciable fraction of the animal's life, which makes it close to a lifetime exposure study. The exposure was 22 hours/day, 7 days/week. Assume that a Wistar rat will respire about 100 ml/min of air and that the average body weight was about 175 grams. At the no tumor level of 50 $\mu g/m^3$ then the daily dose was:

$$100\ ml/min \times 1320\ min \times 50\ \mu g/m^3 \times 1\ m^3/10^6\ ml\ /\ 0.175\ Kg = 37.7\ \mu g\ Cr^{+6}/Kg$$

The exposure level that produced tumors in 3/19 animals was 100 $ug/m^3$ or 75.5 $\mu g\ Cr^{+6}/Kg$ by a similar calculation. These are lower than the 87.5 $\mu g\ Cr^{+6}/Kg$ for the no tumor level for exposure to sodium dichromate by intratracheal instillation but the exposure was 22 hours a day 7 days a week giving very little recovery time for the animals and the exposure groups were small so there is a significant statistical uncertainty.

Considering either the Steinhoff or Glaser studies, a calculated risk based on the effect frequency at the highest daily exposure would be considerably greater than that calculated from the next lower daily exposure. We believe that the same effect occurs when humans are exposed to Cr(VI) and consideration of this should be taken when estimating risk at very low exposure levels based on effects at much higher exposure levels. This type of response is discussed for the Painsville cohort in a recent paper by Proctor *et al.* (2004). One way of improving the risk assessment might be to exclude from the cohort used in the risk calculation any member for which there is information that they were subjected to a very high exposure level for some extended period of time. For example, perhaps cohort members that are assigned exposure values greater than the present PEL or some multiple of it for more than a year would not be considered in calculating the exposure-cancer response relationship. We are not aware of any study that has done this type of analysis but we believe that it should be a way of better estimating the risk for exposures in the range that OSHA is considering for the PEL.

**20. OSHA, in its Preliminary Economic Analysis, has estimated, by application group, compliance costs per affected entity and the likely impacts on revenues and profits under alternative market scenarios. OSHA requests that affected employers provide comment on OSHA's estimate of revenue, profit, and the impacts of costs for their industry or application group. Are there special circumstances—such as unique cost factors, foreign competition, or pricing constraints—that OSHA needs to consider when evaluating economic impacts for particular application groups? Comments are requested on OSHA's analysis of economic feasibility in the PEA.**

We believe that for many of the industries potentially affected by this rule including the chromate chemicals production industry, the products produced are marketed and traded on a worldwide basis. Consequently, the prices set for these products result from global marketing conditions, and are not the result simply of production costs. Accordingly, OSHA's assumptions about cost pass-through for many industries where the end products are marketed worldwide, or where foreign competition threatens U.S. markets, are flawed. Rather, an increase in production costs results in a reduction in the profitability of the product, thereby reducing the industry's profit margin and the viability of U.S. operations.

For example under current market conditions approximately one half of the hexavalent chromium products that our company produces in the U.S. are exported. Additionally there are significant imports of hexavalent chromium chemicals into the U.S. These products, chromic acid and sodium dichromate, are essentially commodity chemicals competing with similar chemicals produced in a variety of other countries including Turkey, Kazakhstan, South Africa and China. Consequently the prices that we are able to charge for our products are dependent on the world market price. Any increase in production cost due to having to meet requirements in a Workplace Exposure Rule for Cr(VI) must come directly from profits or contribute to an increase in losses associated with the sales.

33. **OSHA has proposed a TWA PEL for Cr(VI) of 1.0 µg/m3. The Agency has made a preliminary determination that this is the lowest level that is both technologically and economically feasible and is necessary to reduce significant risks of material health impairment from exposure to Cr(VI). Is this PEL appropriate and is it adequately supported by the existing data? If not, what PEL would be more appropriate or would more adequately protect employees from Cr(VI)-associated health risks? Provide evidence to support your response.**

We do not believe that OSHA has demonstrated that the proposed PEL is both technologically and economically feasible for all of the industry sectors that will be impacted. In the preamble of the proposed rule OSHA indicates that approximately half of the workers potentially impacted by this rule are in the welding, plating and painting industries. These industries have a large number of small operations each with their own specific problems in installing engineering and administrative controls to meet the proposed rule. With the proposed PEL being so much lower than the present standard, we do not believe that the limited number of OSHA site visits were sufficient to accurately determine the feasibility of achieving a PEL of 1 $\mu g/m^3$ in all the industries covered by the proposed rule.

OSHA's basis for the proposed Cr(VI) PEL and establishing a comprehensive standard is based in large part on studies of elevated risk of lung cancer for workers exposed to hexavalent chromium, especially those exposed during the period of 1930-1970, in the chromate chemicals production industry. Several studies of this industry demonstrated a significantly elevated risk of lung cancer especially for those workers with the highest exposures. These studies, however, in our view, are not adequate to develop numerical risk assessments for exposure to hexavalent chromium in all industries. We have discussed this in previous submissions and present additional arguments later in these comments. Most importantly, the numerical risk calculations used by OSHA are based on data from one small industry (currently fewer than 200 total employees in the United States). It is very unlikely that the high exposure levels and the types of compounds to which workers were exposed in the chromate production industry in the 1930s through the 1970s are representative of the current exposures to hexavalent chromium in either this or other industries.

**Other Issues:**

**Sampling Method for Cr(VI)**

The economic and technical feasibility analysis for this proposed rule is largely based on a series of site visits conducted by OSHA and its contractors. To evaluate exposure levels present during the visits, industrial hygiene sampling was conducted. We believe that most of the exposure levels determined were based on results from using OSHA Method ID-215 or a variation on it. Because of this we are concerned about the use of this information in the economic and technical feasibility evaluations. Ashley *et al.* (2003) reviewed potential problems associated with various analytical methods used to determine workplace exposure to hexavalent chromium and many of these are relevant to the OSHA method. However, we are more concerned about the type of sampler and the sample handling techniques used. The sample assembly described in Section 2.1.4. of ID-215 is a two-piece polystyrene cassette holding a 37-mm diameter PVC filter. Although this type of sampling cassette is widely used, a number of studies demonstrate the substantial limitations of the method. These limitations are especially significant when sampling aerosols with a range of particle sizes or when there is significant air movement in the breathing zone such as might be found when measuring exposures outside or in close proximity to local exhaust ventilation. The U.S. Air Force recognized this problem and in response developed a modified version of the 37-mm cassette (Carlton, 2003).

The classic paper by Mark and Vincent (1986) discusses the variability in collection efficiency of different types of samplers when sampling airborne dusts. It must be remembered that airborne Cr(VI) is nearly always present in a dust or mist aerosol with a distribution of particle sizes. Gaseous forms of Cr(VI) are extremely rare. Consequently the sampler needs to be able to collect these different sizes and densities of aerosols with equal efficiency under a range of air movement conditions. Figure 3 of the Mark and Vincent paper illustrates the importance of the size and number of openings in the sampler when sampling a range of particle sizes under a range of air movement conditions. A number of international bodies now specify the "IOM" sampler developed by Mark and Vincent or a similar one in a variety of methods to address these problems. There is detailed information given in Method ID-215 on the steps taken to validate the analytical aspects of this method however we are not aware of what was done to ensure that a representative sample of the workplace exposure is obtained by the sampling equipment used in the site visits.

An aspect of the sampling technique that appears to be well documented in OSHA Method ID-215 is the handling of the filter paper and cassette after sampling. In the analytical portion of the method are the instructions to "Carefully remove each PVC filter from their cassettes or balance..." No mention is made of removing any material that may have clung to the inside of the cassette. This material, which could contain measurable Cr(VI), was in the air stream brought into the sampler and therefore should be considered part of the sample. Table 2 of the publication by Mark and Vincent shows a determination of the fraction of the total mass of dust that entered a sampler that was lost on the internal wall of the sampler. The "Single (4 mm) hole sampler" they tested is somewhat similar in design to the type of cassette sampler referenced in method ID-215. Under the conditions tested by Mark and Vincent as much as forty percent of the sample was lost on the internal wall. They also note that this effect is very variable even under controlled laboratory conditions. The effect was greater for large particle sizes than for small. We do not know exactly how the conditions in this study correspond to the conditions during the site visits but believe that they could be similar to at least some of the conditions OSHA encountered. Recent studies by Demange *et al.* (2002), Clinkenbeard *et al.* (2002) and Li *et al.* (2000) also demonstrate the importance of including the material on the inside wall of the 37-mm cassette in the analysis. Another concern is about the possible effect of electrostatic charges that can build up in non-conductive sampling equipment such as the polystyrene cassette specified in ID-215. As noted by Mark and Vincent, this can also cause inconsistency and error in sampling.

Although we are not aware of any published studies comparing a sampler just like the one identified in Method ID-215 to other types of samplers in the determination of Cr(VI) exposures, studies in other workplaces have shown that sampling results using the standard 37-mm closed-face cassette can differ markedly from those obtained with other types of samplers. For example a side-by-side comparison in the primary nickel production industry of the 37-mm closed-face cassette and the IOM sampler showed that the IOM sampler consistently gave higher results by a factor of 1.2 to 4 (Tsai *et al.*, 1996; Tsai and Vincent, 2001). Kerr et al. (2002) studied exposures in several carbon black production plants and reported that the IOM sampler consistently determined higher exposure levels by about a factor of three than the closed-face 37-mm cassette. Recent publications have discussed the impact that different types of personal samplers used for determining workplace exposures have on the ability of facilities to meet regulatory limits (Werner *et al.*, 1996; Carlton, 2003). Because of the significance of the sampling method used, we believe that OSHA should clearly identify the assumptions made in using the exposure data that was collected in the site visits for the technical and economic feasibility evaluation for this rule.

The proposed rule specifies that: "The employer shall use a method of monitoring and analysis that can measure chromium (VI) to within an accuracy of plus or minus 25 percent (+-25%) and can produce accurate measurements to within a statistical confidence level of 95 percent for airborne concentrations at or above the action level." We do not believe that the method used by OSHA to determine the economic and technical feasibility of the proposed rule has been demonstrated to meet these requirements. Consequently we believe that the information gathered during the site visits misled OSHA about the technical feasibility of achieving the proposed PEL in many workplaces.

We are also concerned about the impact that this could have on enforcement. If a facility does not use exactly the same sampling method as OSHA will use in an investigation, there could easily be conflicts about whether or not a facility is in compliance with the PEL. As OSHA has reported in Table IX-2 of the proposed rule, many exposures are expected to be within a factor of two to five of the proposed PEL. As illustrated in Figure 3 of Mark and Vincent (1986), differences in the results due to the sampling equipment used could be this large for some types of exposures.

Consequently, we believe that it is critical that OSHA specify in detail the method of sampling which they adopted during their studies to prepare the Proposed Rule and specify that the same method will be used to determine future compliance even if it is not mandated for routine sampling, acknowledging that differences will probably exist.

**Types of Exposures in Chromate Chemicals Production**

On page 59384 is the statement "The high-lime process was not used at the Baltimore plant and the 1953 USPHS survey detected minimal levels of less soluble Cr(VI) at this facility." Our reading of the 1953 USPHS survey does not agree with this interpretation. We do not see where the Baltimore facility was identified in that document. Elsewhere in the preamble there is a reference to a 1949 USPHS survey for the Baltimore facility that we have not seen and may be the basis of this statement.

For many years the general understanding in the industry was that except for a period in the early 1970's, the Baltimore plant operated with a feed mix to the roasting kilns having a ratio of lime to ore of about 0.5. Most people in the chromium chemicals production industry would refer to this as a "high-lime" feed mix. A few might call it a "medium-lime" mix but it certainly was not a "low-lime" or "no-lime" mix which is generally refers to mixes having a lime to ore ratio of 0.1 or less. Table 4 of the 1953 PHS document shows results for "a plant using the lime process" indicating very small amounts of Cr(VI) in the Acid Soluble—Water Insoluble portion. We do not believe that this necessarily represents the conditions at the Baltimore facility. If this data was not obtained from the Baltimore facility but instead a facility employing a "low-lime" process, the amount of poorly soluble chromium compounds present would be considerably less than with higher amounts of lime. Even if it was obtained from the Baltimore facility, it is not clear from the descriptions in the Appendix of the 1953 PHS document of the analytical methods used that an accurate determination of species present would have resulted. It is generally known in the industry that chromite ore processing residues (COPR) from facilities using substantial amounts of lime in the feed mix, such as the lime to ore ratio of approximately 0.5 used at the Baltimore facility, contain Cr(VI) that slowly dissolves and tends to be released over many years when exposed to the environment. Remediation efforts for sites containing these types of residues must take this into consideration. We believe that these same types of compounds were present in the ore residue dusts that the workers were exposed to in the Baltimore plant.

There are other aspects of the exposures in the older chromate chemicals production facilities such as the Baltimore and Painsville plants that are specific to this type of facility. For example the high alkalinity of the dust produced from some of the processes. The roast as it discharges from the kiln contains unreacted soda ash and if lime was used, residual lime. These are both very alkaline and may be able overwhelm the buffering capacity of lung fluids if the exposures are high enough. In the older plants it was typical for this roast to be handled in several pieces of equipment before water was added to initiate leaching. There were usually coolers, conveyors, and sometimes mills that the roast went through to make it more suitable for leaching. Each of these was a potential source for very alkaline dust containing Cr(VI) and perhaps other oxidation states of chromium intermediate between Cr(III) and Cr(VI). In modern plants the roast is usually discharged from the kiln directly into a "quench" tank where it is immediately slurried with water greatly reducing the amount of dust formation. The 1953 PHS document reports that the geometric mean particle size of airborne dust in the roasting and leaching area of a chromate-producing plant was about 0.35 microns. This small particle size would have a high likelihood of penetration deep into the lung. These very small particle size, very alkaline exposures are unique to this industry and may be important in understanding carcinogenicity of Cr(VI) in these facilities. For example it is known that the ability of Cr(VI) to penetrate skin tissues in vitro is very dependent on pH (Gammelgaard et al., 1992). Skin tissue is much more permeable to chromate ions at high pH than at neutral or near neutral pH. Possibly the ability of chromate ions to enter critical cells in the lung is also related to the pH environment of the cell.

As we have discussed in previous submissions, we think that it is very likely that the exposures assigned to workers in the studies of these older plants underestimated the actual exposures. The potential problems with the RAC sampler used at the Baltimore plant have been discussed previously as well as some of the problems associated with converting area samples into worker exposure estimates. In addition to was has been said before we would like OSHA to consider the points raised in the discussion above about the difficulty in obtaining a representative sample of an aerosol over a wide range of particle sizes. As noted in Ashley et al. (2003), impingers, which were used extensively in both plants for IH sampling, often give poor recoveries. Factors such as the size of the orifice on the sampler, the orientation, the flow rate through the orifice and air movement velocities in the area sampled all can affect the efficiency of the sampler. These types of sampling inefficiencies in the equipment used for IH sampling in these plants likely led to an underestimation of exposure levels and therefore and overestimation of risk.

**SECALS**

Because of the wide variety of exposures to Cr(VI) we again urge OSHA to consider the use of SECALS. SECALs are separate engineering control air limits that are substituted for the PEL where it is infeasible for either a particular industry or, more likely, a particular operation or job task, to reach the PEL with engineering controls. A SECAL is simply a higher exposure value that can be reached feasibly with engineering controls. The employer would be required to protect those employees in jobs for which a SECAL is adopted to the same level as the PEL, however, that protection can be achieved through the use of respirators rather than engineering controls. We recognize that OSHA appreciates that respirators will need to be used in most industries even after Engineering and Work Practice Controls have been applied (*e.g.* Table IX-3 of the preamble). However, the use of SECALS would reduce uncertainty on how compliance can be achieved in many facilities.

Adoption of SECALs for certain job tasks, such as welding, for instance, would not dramatically change the current proposal, but, rather, would provide significant relief to a myriad of businesses, many of them small, across a broad range of industries. As the standard is currently drafted, engineering controls must be put in place to achieve the PEL or, if it is infeasible to reach the PEL, engineering controls must reach the lowest level feasible. Respirators are then allowed and required to lower any actual exposure to the PEL. Inclusion of SECALs for certain job tasks or operations would simply allow for the use of respirators (rather than the much more expensive engineering controls) to bring an employee's exposure down from the SECAL level to the PEL. In some of these operations engineering controls may be feasible but extremely expensive and their effectiveness in achieving the PEL may not be able to be accurately determined until after they are installed.[1]

**Conclusion:**

The PEL proposed in 69FR59306 is not justified by the available health information and the economic and technical feasibility analyses used to support it are severely flawed.

[1] OSHA adopted SECALs for certain job categories in the cadmium standard (29 C.F.R. § 1910.1027(f)(1)(ii). The regulated community has found the cadmium SECALs provide significant relief to the businesses that have operations covered by the SECALs.

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