Ref: REACH Committee discussion regarding authorisation for uses of two lead chromate paints

Brussels, 1 July 2016

Dear Sir/Madam

With regards to the discussion and possible vote during the next REACH Committee Meeting on 6-7 July on the authorisation for uses of two lead chromate pigments and paints, we would like to draw your attention to the following points:

- New scientific evidence published in the May 2016 issue of Environmental Science & Technology indicates that risks from exposure to lead chromates in pigments and paints are severely underestimated in the application for authorisation and RAC's opinion.

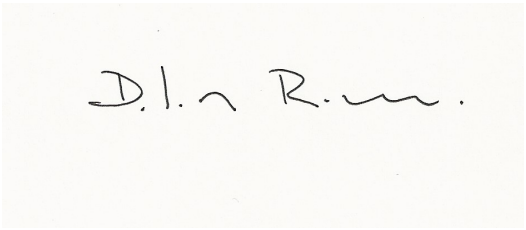
- European paint companies have already ceased the manufacturing of lead chromate paints and have demonstrated the availability of alternatives for the downstream uses applied for. Granting an authorisation to import lead chromates from outside the EU will undermine these EU companies' efforts and investments in safer alternatives.

- The proposed authorisation conditions rely on protective equipment for workers. It is well known that SMEs, which are the downstream users of the paints subject to these authorisations, do not have the adequate training and knowledge to ensure a proper implementation of these measures.
- Granting an authorisation will undermine the efforts of the World Health Organization and the UN Environment Programme's Global Alliance to Eliminate Lead Paint. It would likely

delay many countries taking action to ban lead paint, and prolong the process in countries where action has already been initiated.

Further details can be found in the attachment to this letter. We urge that the Commission and REACH Committee members consider the new scientific evidence in evaluating the authorization. We ask you therefor to reject the granting of an authorisation for the uses of the lead chromates pigments and paints.

Yours faithfully,



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On behalf of:

ClientEarth
The Danish Ecological Council
ECOCITY
Ecologistas en Acción
The European Environmental Bureau (EEB)
Friends of the Earth Germany-BUND
Health and Environment Alliance (HEAL)
Health Care Without Harm (HCWH) Europe
Occupational Knowledge International (OK International)
RightOnCanada
Women in Europe for a Common Future (WECF)
ZERO – Associação Sistema Terrestre Sustentável

Annex

We would like to share new scientific evidence that indicates a much higher level of human exposure to lead that contradict applicants' assumptions and the results of the risk assessments that form the basis of the ECHA Committees' opinions.

Arguments put forward by Dominion Colour Corporation (DCC) under the REACH authorisation application request focus on the low solubility of lead chromate and therefore assume that this compound is not bioavailable. These assumptions were then used in the risk assessment provided by DCC. The Risk Assessment Committee (RAC) accepted the presumption that lead chromate has low solubility and permitted the applicant to adjust the reference dose response relationship for hexavalent chromium accordingly stating:

"The applicant used this dose response relationship, but adjusted it to compensate for the low bioavailability of Cr(VI) as a result of the low solubility of the pigments" (ECHA/RAC/SEAC: : AFA-O-0000004723-74-20/D and ECHA/RAC/SEAC: AFA-O-0000004723-74-17/D Date: 11 December 2014)In addition, the supporting document for listing lead sulfochromate yellow as a substance of very high concern indicates that this pigment is "not soluble" (27 November 2009). The RAC also accepted calculations from Health Canada that similarly concluded that: "the pigments have a low bioavailability (mainly because of a very low solubility) and therefore would also be unlikely to bioaccumulate significantly". The RAC concurred indicating that: "the low solubility of C.I. Pigment Yellow 34 is indicative of limited bioavailability".

The RAC also went on to cite limited experimental data of bioaccessibility. However, the studies cited focused on chromium and lead content in animal models, but only tested for lead in blood, kidney, urine, faeces, various tissues, and lungs. The toxiocokinetic properties of lead have been extensively studied and it is well known that bone is the largest reservoir of lead in the body. (Rabinowitz MB. Toxicokinetics of bone lead. *Environmental Health Perspectives*. 1991;91:33-37.) Lead in bone is released over time to the blood and soft tissue and it is know that the mobilization from bone accelerates significantly during pregnancy.

The first ever study examining the bioavailability of lead chromate in bone in an animal model has recently been published and suggests that earlier assumptions that low solubility would equate to limited bioavailability may have been made in haste. (see: Zhao, Di, et al. "Lead relative bioavailability in lip products and their potential health risk to women." Environmental science & technology 2016). The study indicates that approximately one-third of lead chromate in lipstick (and about 45% of all lead compounds used in lipstick) is bioavailable in bone in an animal model. This information, if used in the risk assessment for lead chromate, would require an assumption of a much higher dose and ultimately impact the derived risk level.

We urge that the Commission and REACH Committee members consider this new scientific evidence in evaluating the authorisation. In particular, any risk assessments that relied on incorrect assumptions of limited bioavailability of lead chromate pigments must be revised to account for this experimental data.

Furthermore, the proposed authorisation conditions rely on protective equipment for workers. It is well known that SMEs, which are the downstream users of the paints subject to these authorisations, do not have the adequate training and knowledge to ensure a proper implementation of these measures. More importantly, EU worker protection legislation clearly establishes that this should be the last resource to protect workers from exposure to carcinogens, with substitution being the first means.

European paint companies and authorities have demonstrated the availability of alternatives for the downstream uses applied for. In fact, the European industry has already ceased the manufacturing of these paints in line with the goal of the World Health Organization and the UN Environment Programme's Global Alliance to Eliminate Lead Paint. Granting an authorisation will undermine these companies efforts and investments in safer alternatives. Moreover a number of EU MS have already prohibited the use of these paints.

Granting an authorisation to continue the use of lead chromated paints would not only mean more lead pigments being sold, but it would send a very bad signal to all countries that have not yet enacted any regulations on lead paint. It would suggest that if not even the EU can completely ban the use of lead chromates, how would a developing country or a country in transition be able to do so? This would likely delay many countries taking action to ban lead paint, and prolong the process in countries where action has already been initiated.

Therefore, we ask you to reject the granting of an authorisation for the uses of the two lead chromate paints.