American Chemistry Council | Chlorine Chemistry Division

December 15, 2015

Information Quality Guidelines Staff
Mail Code 2811A
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Information Quality Act Request for Correction of the TSCA Work Plan for Chemical Assessments: 2014 Update (October 2014) and the TSCA Work Plan Chemicals: Methods Document (February 2012) regarding assessment of 1,2-dichloroethane (ethylene dichloride, CAS number 107-06-2)

Dear Sir or Madam:

The Chlorine Chemistry Division (CCD) of the American Chemistry Council (ACC) submits this Request for Correction to EPA under its *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency* (IQ Guidelines).[1] This request seeks the correction of numerous factual errors in the above referenced documents developed for the Office of Pollution Prevention and Toxics (OPPT) TSCA Work Plan Chemicals Assessment Process related to potential exposure to, and environmental persistence of, 1,2-dichloroethane (ethylene dichloride or EDC).

CCD represents the major chlor-alkali manufacturers in North America who produce about two-thirds of the EDC made in the US and Canada.[2] It is estimated that 99 percent of EDC is used as a chemical intermediate in the production of vinyl chloride monomer (VCM)[3] nearly all of which goes into production of polyvinyl chloride (PVC).[4]

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1 EPA, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA/260R02008 (October 2002).

2 ACC's Chlorine Chemistry Division members include Axiall Corporation, The Chemours Company, Covestro LLC, DuPont, Olin Corporation, and Occidental Chemical Corporation.

3 See European Chemicals Agency (ECHA). Background Document for 1,2-dichloroethane - Document Developed in the Context of ECHA's Fourth Recommendation for the Inclusion of Substances in Annex XIV (November 29, 2012). Available at http://www.echa.europa.eu/documents/10162/38c352db-d89e-472f-9539-4fec08c6ca34.

4 EPA. Vinyl chloride (75-01-4) – hazard summary. Office of Air and Radiation (January 2000). Available at http://www3.epa.gov/ttn/atw/hlthef/vinylchl.html.

As set forth in the IQ Guidelines, information is objective when it is "presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased."[5] In its TSCA Work Plan documents, OPPT presents information on EDC that is not accurate and fails to meet the requisite standard of objectivity. OPPT has indicated that it uses this Work Plan assessment to focus the activities of its Existing Chemicals Program so that those chemicals having the highest potential for exposure and hazard are assessed and, if warranted, are subject to risk reduction actions. The accuracy of the information presented in the Work Plan, therefore, will determine the scientific integrity of the Agency's assessment and any actions resulting from that assessment, as well as the message that these actions convey to the marketplace and general public.

Correction of the data included for EDC under OPPT's Work Plan, as described in this Request, makes it clear that the substance should not be included in the TSCA Work Plan Chemicals Assessment Process. Since OPPT has indicated its intention to assess each of the Work Plan Chemicals under TSCA, and has provided no other opportunity for comment on the inclusion of EDC, CCD is submitting this Request to ensure that the inaccuracies described herein are corrected in a timely manner. As outlined below, these comments focus on OPPT's assessment of potential exposures to EDC and the substance's environmental persistence.

Based on the information presented here, EDC should be removed from the TSCA Work Plan Chemical Assessment Process.

Background

In 2011, OPPT sought comment through an online discussion forum,[6] stakeholder forum and webinar on a Discussion Guide[7] that outlined the two-step process the Agency intended to use to identify and rank Work Plan chemicals.[8] ACC participated in and commented on the process, encouraging OPPT to ensure that its prioritization followed a "robust, comprehensive and science-based" process. In February 2012, OPPT released a Methods Document that further described the prioritization process and identified - for the first time - 83 chemicals for assessment. Seven of the chemicals were targeted for priority review in 2012. The remaining 76 (including EDC) were identified as "Additional Work Plan Chemicals" without a timeframe for

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5 IQ Guidelines, at 15.

6 http://blog.epa.gov/chemprioritization/.

7 EPA. Discussion Guide: Background and Discussion Questions for Identifying Priority Chemicals for Review and Assessment (August 2011). Available at http://www.epa.gov/oppt/existingchemicals/pubs/Chem.Priorization.August2011.DiscussionGuideOnly.pdf.

8 EPA. TSCA Work Plan Chemicals: Methods Document. Office of Pollution Prevention and Toxics (February 2012), at 2. Available at http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf.

assessment. The Methods Document included numerical scores for Hazard, Exposure, and Persistence and Bioaccumulation for all the listed chemicals, but it provided little explanation for the scores beyond the general methodology used by OPPT and brief descriptions of "Criteria Met" in the three categories.

The Methods Document provides a normalized total score of 7 for EDC resulting from a Hazard score of 3 ("High"), an Exposure score of 2 ("Moderate"), and Persistence and Bioaccumulation score of 2 ("Moderate").[9] Based on the total score of 7 for EDC, the Methods Document indicated that EDC was a priority for review under the TSCA Work Plan Chemicals categorization scheme.

In October 2014, OPPT released an update to the Methods Document (2014 Update)[10] that removed 13 substances from the list of Work Plan Chemicals because "they no longer present exposure potential from consumer or commercial use." Mercury and mercury compounds were also removed because their hazards "are well characterized and EPA has a strong risk reduction effort in place."[11] Quartz was removed because the hazards associated with it are limited to the workplace and controlled by regulations issued by the Occupational Safety and Health Administration. Other chemicals were added based on OPPT's conclusion that the potential for exposure was greater than originally concluded.

Although the description for EDC in the summary table in the 2014 Update did not change, the Exposure Score was increased to 3 ("High") - pushing the total score for EDC from 7 to 8. The Hazard and Persistence/Bioaccumulation scores were unchanged. No explanation was offered for the increase in Exposure Score other than a general statement in the 2014 Update that "[t]he changes to the TSCA Work Plan for Chemical Assessments reflect updated industry data submitted to EPA through the Toxics Release Inventory (TRI) in 2011 and the TSCA Chemical Data Reporting (CDR) requirements in 2012 on chemical releases and potential exposures."[12] However, as explained in detail below, the cumulative evidence on EDC indicates that its overall Exposure Score should be reduced to 1.

Change in Exposure Score for EDC in the 2014 Update

CCD is perplexed by the increase in EDC's Exposure Score from 2 ("Moderate") in the Methods Document to 3 ("High") in the 2014 Update. As described in the OPPT methodology, the

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9 Methods Document, Appendix D.

10 EPA. TSCA Work Plan for Chemical Assessments: 2014 Update. Office of Pollution Prevention and Toxics (October 2014). Available at http://www.epa.gov/oppt/existingchemicals/pubs/TSCA_Work_Plan_Chemicals_2014_Update-final.pdf.

11 2014 Update, at 7.

12 2014 Update, at 2.

highest Overall Exposure Score that a commercial/industrial chemical (with no consumer applications) like EDC can achieve under the OPPT methodology is 2 – regardless of changes in the TRI and CDR data.[13] Since OPPT's evaluation in the Methods Document presumably had already accounted for the fact that TRI releases of EDC exceed 100,000 pounds/year, changes in the 2011 TRI or 2012 CDR data could not affect the exposure score any further.

OPPT Composite Exposure Score of EDC

The Methods Document explains that the Exposure Score is calculated by aggregating rankings for three sets of criteria:

- Chemical Use – consideration of the types of users (industrial, commercial, general public) of the application that could result in exposure;
- General Population and Environmental Exposure – measured data on the presence of a chemical in biota and environmental media; and
- Release – data from TRI or CDR information for chemicals not subject to TRI reporting.

OPPT's Work Plan summary indicates that EDC meets the following Exposure criteria:

- Used in commercial/industrial products;
- Present in biomonitoring, drinking water, indoor environments, surface water, ambient air, groundwater, soil; and
- High reported releases to the environment.

Based on the OPPT assessment, the 2014 Update assigned EDC a normalized overall Exposure Score of 3 corresponding to an overall rank of "High" for potential exposure. As described above, this overall score is inconsistent with the methodology outlined in the Methods Document from which EDC could be assigned an Exposure Score no higher than 2. In addition, OPPT has significantly overstated the presence of EDC in biota and the environment, and the potential for widespread exposures from TRI releases.

Current EDC Use is Limited to Consumptive Applications

We agree with OPPT's use characterization of EDC as commercial/industrial product with no consumer product uses. This view is confirmed by a search of Work Plan data sources which finds no records of EDC as an ingredient in consumer products.

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[13] According to the Methods Document, a commercial/industrial chemical can be assigned a Use Score no higher than 1. Assuming that EDC is assigned the highest score of 3 for both the General Population/ Environmental Exposure Criteria and the Release Criteria, it could be assigned a Total Exposure Score no higher than 7. As a consequence, EDC would be assigned a Normalized Overall Exposure Score no higher than 2 and Overall Rank of Moderate according to the Methods Document.

Other uses of EDC noted in the literature as an ingredient in products such as gasoline (for lead scavenging), paint solvents, coatings, adhesives and grain fumigants have been discontinued, according to several sources.[14,15]

Today, it is estimated that more than 99% of EDC manufactured in the U.S. serves as an intermediate in the production of VCM which is subsequently converted into PVC which goes into a wide variety of applications.[16] The remainder is consumed in the production of chlorinated solvents and ethyleneamines.

Manufacturer specifications for VCM require that only very low residual levels of EDC (i.e., 0.05 to 10 parts per million or ppm) remain. In the subsequent conversion of VCM to PVC resin, the resin is heat-treated to strip residual VCM down to low ppm levels.[17] As a consequence there is no potential for EDC exposure from commercial and consumer applications of PVC.

OPPT's Evaluation Overstates the Potential for General Population and Environmental Exposure

OPPT's characterization of the general/environmental exposure criteria for EDC suggests that the substance has been widely detected in biomonitoring, drinking water, indoor environments, surface water, ambient air, groundwater, and soil.[18] This characterization is inconsistent with the data available from the sources cited in Appendix B of the Methods Document. In particular, the Fourth National Report on Human Exposure to Environmental Chemicals (February 2015) reports that blood monitoring during the 2003-2004 and the 2005-2006 sampling cycles of the National Health and Nutrition Examination Survey (NHANES) failed to detect EDC in over 4,300 individuals covering the full range of ages, gender, and race/ethnicity.[19] This conclusion from the Centers for Disease Control and Prevention's (CDC) nationally representative biomonitoring data base directly contradicts OPPT's analysis and indicates that the potential for exposure to EDC in the general population is minimal.

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14 Agency for Toxic Substances and Disease Registry (ATSDR). Toxicological Profile for 1,2-Dichloroethane. US Department of Health and Human Services, Public Health Service (September 2001). Available at http://www.atsdr.cdc.gov/ToxProfiles/tp38.pdf.

15 California Air Resources Board. Indoor Air Pollution in California (July 2005). Available at http://www.arb.ca.gov/research/indoor/ab1173/rpt0705.pdf.

16 IHS Chemical. Chemical Economics Handbook – Ethylene Dichloride. CEH Report 651.5000. (September 2015).

17 The residual specification for VCM may vary depending on the PVC application.

18 Appendix D of the Methods Document provides no specific source for information on the presence of EDC levels in indoor environments or soils.

19 CDC. Fourth National Report on Human Exposure to Environmental Chemicals (February 2015), at 507. Available at http://www.cdc.gov/biomonitoring/pdf/FourthReport_UpdatedTables_Feb2015.pdf. According to CDC, the limit of detection for EDC is 0.01 nanograms per milliliter of blood.

In light of the fact that EPA established a maximum contaminant level (MCL) for EDC under the Safe Drinking Water Act (SDWA), it is not surprising that EPA has collected data on drinking, surface, and ground water levels of EDC. It is notable, however, that the National Contaminant Occurrence Database (NCOD) indicates that the substance was detected in only about 2,000 of the 375,000 samples (0.56%) collected by the Agency. Of the 2,000 detections, only 99 exceeded the MCL of 5 parts per billion (ppb). That number of exceedances represents about 5% of the detections and 0.03% of all of the samples. As a result of these very small numbers of detections, EPA concluded that the potential for exposure in drinking water to EDC is minimal and that the MCL for EDC was appropriate and required no further review under the SDWA.[20]

Similarly, the designation of EDC as a hazardous air pollutant (HAP) under the Clean Air Act has resulted in monitoring and modeling of ambient levels of the chemical. While the Methods Document did not identify any EPA sources for monitoring data among the sources used for exposure scoring, the World Health Organization[21] reports that background concentrations of EDC in Europe and North America were about 0.2 micrograms per cubic meter ($\mu g/m^3$), and that levels in urban areas ranged from 0.4 to 1.0 $\mu g/m^3$. These values are higher than more recent data collected by the New York State Department of Environmental Conservation where the maximum level of EDC detected at multiple sites was 0.03 parts per billion (0.12 $\mu g/m^3$).[22] One additional source of monitoring data available from EPA that was not identified in the Methods Document is the 2005 National Air Toxics Assessment (NATA) conducted by the Agency's Office of Air and Radiation. According to the background document provided with the 2005 Assessment, 96% of the 267 ambient samples analyzed for EDC were below the method detection limit.[23] The NATA results are described in more detail in the next section.
A search of data sources in the Methods Document suggests that many, if not most, of the media that the Work Plan associates with "presence" of EDC relate to legacy/outdated practices and do not reflect today's product uses, manufacturing regulations, industry standards and compliance practices, or likely exposure pathways. Considering the scarcity of measurable levels of EDC, OPPT's list of multiple media in which the substance may be present unfairly characterizes actual risks from the chemical and leads to an overstated ranking. As described, there is no detectable body burden from biomonitoring, and the potential for

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20 75 *Federal Register* 15499-15572 (March 29, 2010).

21 World Health Organization (WHO). Air quality guidelines for Europe. WHO Regional Publications. European Series, No.91. 2nd edition. WHO Regional Office for Europe. Copenhagen (2000).

22 The Methods Document identified ambient air monitoring data collected by New York State and the California Air Resources Board (ARB) as data sources. According to the ARB web site, the agency stopped analyzing for EDC in 1995. New York State data are available at http://www.dec.ny.gov/chemical/66478.html; California data are available at http://www.arb.ca.gov/adam/toxics/statesubstance.html.

23 EPA. An Overview of Methods for EPA's National-Scale Air Toxics Assessment (NATA Overview). Office of Air Quality, Planning, and Standards Research (January 31, 2011), at 2-21 (Table 2-7). Available at http://www3.epa.gov/ttn/atw/nata2005/05pdf/nata_tmd.pdf.

exposure to the general public from water and ambient air is considered by EPA to be insignificant.

Since biomonitoring data integrates all exposure types (air, food, water, etc.), it provides the most comprehensive evaluation of the potential for exposure to EDC among the general population. The absence of detectable levels of EDC in two consecutive cycles of sampling under NHANES provides a very strong indication that exposure of the general population to EDC is unlikely. This conclusion is confirmed by EPA's evaluation of potential exposure from air and water sources. The preponderance of the evidence therefore points to a General Population and Environmental Exposure ranking of 1 ("present in one environmental medium").

Available EPA Data Show Geographically-Limited Exposure to EDC Releases

The third component of the overall Exposure Score is the Release Score based on TRI releases or, if the substance is not included in TRI, CDR data. TRI reports indicate that about 425,000 pounds of EDC were released in the U.S. in 2014, the most current data year.[24] Although this quantity meets the low threshold for a Release Score of 3 set in the Methods Document (TRI releases >100,000 lbs.), it ignores a significant amount of other information readily available to OPPT.

As the table below shows, TRI reports for the years 2010-2014 show a significant decline in total on-site and off-site EDC releases. In fact, this decline continues a trend that started many years earlier.

Toxic Release Inventory Data for EDC, 2010-2014
(in pounds)

Year	Total Air	Other On-Site	Off-Site Release & Transfers	Total Releases/ Transfers
2010	472,403	37,738	67,236	577,377
2011	395,717	47,823	21,571	465,111
2012	381,227	88,013	2,052	471,291
2013	343,997	70,862	624	415,483
2014	377,404	31,293	16,565	425,261

[24] EPA, TRI Explorer, Trends Report, 1,2-dichloroethane, 2014. Available at http://iaspub.epa.gov/triexplorer/release_trends?p_view=USYR&trilib=TRIQ1&sort=_VIEW_&sort_fmt=1&state=All+states&county=All+counties&chemical=000107062&industry=ALL&year=All+years&core_year=&tab_rpt=1&fld=AIRLBY&fld=E1&fld=E2&fld=E3&fld=E4&fld=E41&fld=E42&fld=E5&fld=E52&fld=E53&fld=E53A&fld=E53B&fld=E54&fld=E51&fld=E51A&fld=E51B&fld=TSFDSP&fld=TSFDSP&fld=m10&fld=m41&fld=m62&fld=potwmetl&fld=m71&fld=m81&fld=m82&fld=m72&fld=m63&fld=m64&fld=m65&fld=m66&fld=m67&fld=m73&fld=m79&fld=m90&fld=m94&fld=m99&fld=RELLBY.

The declining trend in total releases is particularly noteworthy in light of an increase of about 10% in EDC production since 2010 as indicated by CDR reports and confirmed by industry data.[25] Not surprisingly, the increase in EDC production directly tracks the increase in demand for PVC resulting from improving economic conditions.[26]

In addition, it is important to note that the bulk of the EDC releases are to the atmosphere. In 2014, for example, fugitive and point source emissions accounted for 377,404 lbs. (89%) of total releases. Most of the rest of the releases for that year (39,746 lbs., 9% of total) went to disposal (on-site and off-site) by underground injection in a Class 1 well. Only about 2,600 lbs were reported discharged to surface waters -- 0.6% of total releases.

The TRI data also confirm that the vast majority of atmospheric releases resulted from a small number of manufacturing operations. In fact, 20 chemical manufacturing facilities account for 90% of releases to the atmosphere.[27] Given this concentration in environmental releases, it is not surprising that EPA estimates that potential exposures to EDC are limited to a small number of counties and census tracts.

Data developed by EPA under NATA indicate that only 20 of the 66,000 census tracts analyzed were estimated to have total ambient concentrations of EDC of 0.1 $\mu g/m^3$ or higher, representing a total population of 80,463 or about 0.03% of the nation's population. According to the NATA analysis, only 13 of the census tracts were estimated to have exposures to EDC of 0.1 $\mu g/m^3$ or more. These tracts have a combined population of 50,364, representing about 0.02% of the total U.S. population. This information led EPA to conclude that EDC releases were "point-source dominated" and was further supported by the finding that EDC levels were below the Method Detection Limit (MDL) for 96% of samples taken at 267 monitoring locations.[28]

Even in the geographical areas with the largest emissions, moreover, the NATA estimates indicate that EDC exposure is low. The highest ambient concentration of 0.35 $\mu g/m^3$ (0.09 ppb) was predicted in Charleston, SC; the highest exposure to EDC of 0.22 $\mu g/m^3$ (0.06 ppb) was predicted in Brazoria, TX. It is noteworthy that these highest current values are below the

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[25] Data available from the ICIS Chemical Business Service suggest an increase in EDC production of 10 percent from 2010 to 2014.

[26] ACC Plastics Industry Producer's Statistics Group reports that PVC production increased by 5 to 10 percent from 2010 to 2014. Housing starts, a key indicator of PVC demand, began crashing in 2006 and reached their lowest level in decades in mid 2009, at which point they began steadily increasing.

[27] Thirteen of the 20 facilities are engaged in chlor-vinyl manufacturing and themselves account for 80 percent of the total releases to air.

[28] NATA Overview, Appendix F at 2-2 (Table 2-1).

range of levels reported in seven urban locations in 1980-1981 (0.1 to 1.5 ppb).[29] The decline in ambient concentrations and exposures is dramatic but should not be unexpected given the declines in releases from EDC manufacturing.

OPPT Overstates EDC's Environmental Persistence

OPPT assigns EDC a Persistence and Bioaccumulation Score of 2 ("Moderate") based on an estimate of the atmospheric half-life as ≥ 2 months (67 days) from its PBT Profiler.[30] According to other data sources, however, the range of atmospheric lifetime is estimated to be as short as 42 days, and depends on the model chosen.[31] EPA's estimate is at the high end of the range of 42 to 73 days reported by the Organization for Economic Cooperation and Development (OECD).

In estimating atmospheric concentrations for NATA, EPA used a "residence time" of 42 days for EDC.[32] The residence time which incorporates both reaction rates and removal via other pathways may be substantially different than the media-specific half-life for some chemicals and may provide better insight into the substance's overall persistence. According to the PBT Profiler "[t]he overall persistence is the weighted average of the residence time in all media." The Profiler notes that there is an ongoing debate in the scientific community over the best method for assessing overall persistence and explains that "there is no agreement on the criteria that should be applied to the overall persistence."[33]

The atmospheric half-life that OPPT used in assigning a Persistence Score for EDC sits right at the dividing line between 1 ("Low") and 2 ("Moderate") and is on the high end of the range of estimates reported for the substance by OECD. Rather than use an arbitrary cut-off to assess EDC's persistence, OPPT should look at the half-life information in the context of other available information to assess the substance's persistence. Based on such an assessment, it is reasonable to assign EDC a persistence score of 1 ("Low").

EDC is Well-Regulated

As OPPT points out in the Work Plan, "[s]ome chemicals identified as 'high' through this scoring

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29 EPA. Ethylene Dichloride (1,2-Dichloroethane) – Hazard Summary (Revised January 2000). Available at http://www3.epa.gov/airtoxics/hlthef/di-ethan.html.

30 http://www.pbtprofiler.net/Results.asp.

31 OECD. SIDS Initial Assessment Report – 1,2-dichloroethane. 14th SIAM Paris, France (March 2002). Available at http://webnet.oecd.org/hpv/ui/SponsoredChemicals.aspx.

32 NATA Overview, at 2-18 (Table 2-6).

33 http://www.pbtprofiler.net/ChemDetails.asp?I=0.

system may not necessarily be practical candidates for assessment under TSCA when other information is factored into the process. For example, the particular risks presented by certain chemicals may already be addressed by significant regulation under other statutes." Like the substances that were removed from the Work Plan in the 2014 Update, EDC use is well characterized and well controlled, and no longer presents an exposure potential to the general public. In particular, regulatory controls imposed on EDC under the SDWA and Clean Air Act have resulted in a very low potential for exposure to the substance. The unlikelihood for exposure to EDC is underscored by the biomonitoring data collected by CDC under the NHANES program which did not detect the substance in blood collected from individuals over two consecutive sampling cycles.

CCD requests that OPPT revise its conclusions about the potential exposure to EDC to accurately reflect the available information on uses, emissions, and environmental presence and persistence of the substance. Such revision will clearly indicate that the potential for exposure to the chemical is quite low and that review under the TSCA Work Plan Chemicals Assessment Process is not supported by the available information. Consequently, EDC should be removed from the TSCA Work Plan.

Please feel free to contact me at 202-249-6709 or judith_nordgren@americanchemistry.com if you have questions on the above information.

Sincerely,

Judith Nordgren

Judith Nordgren
Managing Director
Chlorine Chemistry Division

cc: W. Cleland-Hamnett, OPPT Director
T. Henry, OPPT Risk Assessment Division