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Via E-Mail and Regular Mail

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Mr. Michael Infurna
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UNITED STATES ENVIRONMENTAL
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Re: RCRA Section 3008(h) Administrative Order on Consent
Docket No. II-RCRA-90-3008(h)-0209
FMC Corporation, Middleport, NY Facility
EPA I.D. No. NYD002126845
Comments on the USEPA, NYSDEC & NYSDOH
FMC-Middleport, Arsenic Soil Contamination FAQs

Dear Messrs. Mortefolio and Infurna:

On September 28, 2007, the New York State Department of Environmental Conservation (NYSDEC), United States Environmental Protection Agency (USEPA) and the New York State Department of Health (NYSDOH) (collectively, “the Agencies”) provided Village of Middleport, New York Mayor Maedl a document entitled “USEPA, NYSDEC & NYSDOH FMC-Middleport, Arsenic Soil Contamination FAQs”. The document presented “Frequently Asked Questions” and the Agencies’ answers concerning FMC Corporation (FMC) related arsenic soil contamination in the Middleport community. That document was subsequently distributed to the Middleport Community Input Group (MCIG) and to attendees at the October 1, 2001 MCIG meeting held at the Middleport fire hall. FMC has reviewed the FAQ document and now provides comments with respect to various statements in this document.

FAQ #1 – How was the 20 parts per million (ppm) local soil arsenic background level determined for Middleport soils?

FMC Comment on the Agencies’ Answer #1 – The FAQ document implies that there has been a formal determination and selection of 20 ppm as the soil arsenic background level for the Middleport area. This is not correct. While the Agencies may be using this value based on the 2002 study in Gasport and the February 2003 report on this study (the Gasport Background Study Report), 20 ppm has not been formally determined or selected as the Middleport soil arsenic background criterion. By letter dated June 25, 2007, FMC provided the Agencies a report entitled “Background Arsenic Soil Concentrations in Middleport, NY” (prepared by Gradient Corporation). That report recalculated the background values for arsenic in Middleport soils that were originally presented in the 2003 Gasport Background Study Report. The background values were recalculated in accordance with agency-



developed and approved methods using information that became available after 2003 resulting in significant adjustments to the weighting factors. As presented in the June 2007 report, the weighted 95th percentile of the 2003 Gasport data set and the 1989 Gasport orchard data set is 49.7 ppm.

The June 2007 report also presented a weighted 98th percentile of 87.4 ppm. Use of the 98th percentile for delineation of potential FMC-related arsenic in soil in the Middleport study area is consistent with the methods used by the NYSDOH and NYSDEC to determine the state-wide arsenic soil background value, as presented in the New York State guidance “New York State Brownfield Cleanup Program, Development of Soil Cleanup Objectives, Technical Support Document” (NYSDEC and NYSDOH, September 2006). The June 25, 2007 letter advised that following the Agencies’ review of the revised and updated background study and agreement with FMC on the appropriate value for RCRA Facility Investigation (RFI) delineation purposes, FMC would be able to complete the RFI work and submit a revised and updated RFI report(s).

FAQ #2 – How and why are the Agencies using the local soil arsenic background level in their remedial decisions?

FMC Comment on the Agencies’ Answer #2 – The FAQ document cites as authority Section 27-1415.6(b) of New York’s Environmental Conservation Law (“ECL”). However, that section does not apply to the FMC Middleport facility RCRA corrective action program. Moreover, that section of the statute and its implementing regulations do not require the universal use of contaminant-specific soil cleanup objectives which do not exceed an excess cancer risk of one in one million (i.e., 1×10^{-6}) for carcinogenic end-points.

The Agencies’ citation to Section 27-1415.6(b) of the ECL as authority for the substance of the rest of the answer is misplaced. The section of the statute cited by the Agencies is part of Article 27, Title 14 of the ECL, which is entitled “Brownfield Cleanup Program.” That article establishes the statutory basis for a voluntary program applicable to “Brownfield sites.” The FMC Middleport facility does not qualify as a “Brownfield site” as that term is defined in ECL Section 27-1405.2, and is not in the State’s Brownfield Cleanup Program. The facility is subject to the above-referenced Administrative Order on Consent (“AOC”) issued on the authority of RCRA §3008(h) and ECL §71-2727(3), which requires that FMC perform a RCRA corrective action program in accordance with the very specific terms of the AOC.

Section 27-1415.6(b) of the ECL should be read and understood in the context of the entire statutory provision. Section 27-1415.6(b) directs the NYSDEC to promulgate regulations which create a multi-track approach for remediation of contaminated sites. Section 27-1415.6(a) requires the regulations to include three (3) generic tables of contaminant-specific remedial action objectives for soil based on current, intended, or reasonably anticipated future use, as follows: (i) unrestricted; (ii) commercial; and (iii) industrial. Section 27-1415.4 specifies the four (4) program tracks that are to be established in the regulations. A remedial program under Track 1 or Track 2 must achieve remedial action objectives for soil which conform to those established in the generic tables. A remedial program under Track 3 must achieve remedial action objectives which are determined using *site-specific data* and the *criteria* used to develop the generic tables, as an alternative to the numeric values in the tables. Section 27-1415.6(b) provides that a site-specific soil cleanup value developed under Track 3 may not exceed an excess cancer risk of 1×10^{-6} , unless the background concentration for the contaminant in rural New York soils exceeds that risk level, in which case the cleanup objective is the background value. A remedial

program under Track 4 expressly recognizes and authorizes the development and use of site-specific soil cleanup objectives which exceed an excess cancer risk of 1×10^{-6} , either with or without the use of long-term institutional or engineering controls, upon a finding by the Commissioner, in consultation with the Commissioner of Health, that such a level will be protective of public health and the environment in that specific case.

The authority to use site-specific and contaminant-specific soil cleanup objectives which may exceed a one-in-one million excess cancer risk is also reflected in the implementing regulations for the Brownfield Cleanup Program. Specifically, those rules provide at 6 NYCRR §375-3.8(a)(3) that “the risk presented by residual contamination ... at a site shall not exceed an excess cancer risk of one-in-one million for carcinogenic end points ..., except:

- (i) for remedies provided in accordance with paragraph (e)(4) below, with a cleanup level which exceeds the parameters in paragraph (3) above, the remedial party must demonstrate that such level would be protective of public health and the environment. ... and
- (ii) a cleanup level which exceeds the parameters in paragraph (3) above, may be approved by the Department in accordance with paragraph (e)(4) below, without requiring the use of institutional or engineering controls to eliminate exposure only upon a site-specific finding by the Commissioner, in consultation with the State Commissioner of Health, that such level will be protective of public health and the environment.”

The RCRA corrective action program that FMC is performing on the authority of the AOC is not governed or constrained by the New York State Brownfield Program statute or regulations. However, even if the latter have some application or relevance, that law and those rules when read in their entirety expressly provide for the development of site-specific and contaminant-specific soil cleanup objectives that are not bounded by an excess cancer risk of one-in-one million.

FMC and the Agencies have informally agreed to use a site-specific value for soil arsenic background from the Gasport background study for the delineation of potential FMC-related arsenic in soil in the Middleport study area. However, as discussed in the above FMC Comment on Agencies’ Answer #1, based on the revised and updated information provided in the report submitted on June 26, 2007, this value is not 20 ppm, but 49.7 ppm (or 87.4 ppm if the 98th percentile is used (consistent with the methodology of NYSDOH and NYSDEC in the September 2006 Technical Support Document referenced in FMC Comment on Agencies’ Answer #1, above)).

FMC agrees with the Agencies that 20 ppm has not been used as “the sole criterion to trigger soil remediation.” Off-site soil remediation projects that have been proposed or performed prior to completion of a Corrective Measures Study (CMS) or Studies have included one or more of the following considerations:

1. Results of a human health risk assessment – USEPA commissioned the performance of a human health risk assessment on the Royalton-Hartland (Roy-Hart) school property and based on the results of the risk assessment, determined in 1998 that remediation of the school football field/track area was necessary and identified the specific aerial boundaries of the remediation area (i.e., football field and track area). The USEPA draft risk assessment (to FMC’s knowledge and recollection a final risk assessment was never prepared or issued) determined that the cancer risk estimate for the football field/track area exceeded the USEPA non-cancer

threshold limit of 1.0 and the USEPA acceptable cancer risk range of 10^{-4} (1 excess cancer in a population of 10,000) to 10^{-6} (1 excess cancer in a population of 1,000,000).¹ The Agencies directed FMC to perform an Interim Corrective Measures (ICM) to remove soil from the school football field/track area. As documented in the Agencies' April 1999 responses to public comments, the Agencies also evaluated the potential human health risks on the entire school property after completion of the ICM. The post-ICM non-cancer and cancer risks were estimated for the entire Roy-Hart school property, including areas from which soil would not be excavated pursuant to the ICM. Based on the result of that evaluation the Agencies stated that they "*consider the "post-ICM" potential non-cancer health risk to students to be below the EPA threshold limit, and the "post-ICM" potential carcinogenic risk to students to be within EPA's range of acceptable carcinogenic risks and similar to the potential carcinogenic risk associated with the local background soil arsenic data set.*" (Agencies "Responsiveness Summary for the Royalton-Hartland School Yard, Interim Corrective Measure" (April 1999)). Following the successful completion of the ICM and a further evaluation of the residual arsenic levels in the school yard soils, the Agencies determined that "the entire school yard is suitable for both athletic and non-athletic uses by all school children, in terms of their exposure to known school yard soil arsenic levels." (Agencies' May 26, 2000 letter to the Roy-Hart School District).

2. Address a potential source of FMC-related contamination – Areas that contain the highest soil arsenic concentrations and that may have a potential for downstream migration of contaminants have been and will be addressed in a manner that will minimize any potential for re-contamination of remediated areas. Off-site areas remediated to date and currently undergoing remediation have been in areas of FMC's historic surface water migration pathways or where deposition from historic air emissions was likely. Remediation projects started in areas closest to the FMC Plant and have moved downstream or away from the plant site. These areas include the Roy-Hart school property, the railroad property along the northern boundary of the FMC plant facility, the 14 Vernon Street residential properties immediately to the west of the FMC plant facility or along the historic storm sewer from the facility, the Wooded Parcel of the Commercial/Industrial area north of the FMC plant facility, and residential properties on Park Avenue (and Maple) immediately north of the Commercial/Industrial Area.
3. Minimize potential human exposures to elevated levels of arsenic in soil – The scope of remediation projects have been conservatively developed to minimize current and potential future human exposures based on current and reasonable future usages and to minimize the potential for performance of any additional remediation once the CMS is completed.
4. Practicability and timing of remediation – The projects implemented and currently underway are ones where the remediation area and scope of work can be completed in one construction season, can be defined based on existing data, can minimize potential future disturbance/remediation of the off-Site property once the CMS has been completed, and can be agreed to by both the Agencies and FMC. Most properties remediated to date contained arsenic in the soil at levels which both FMC and the Agencies have agreed warranted remediation.

¹ FMC did submit comments on the USEPA draft risk assessment pointing out errors and assumptions that caused the risks to be substantially overestimated. The Agencies responded to these comments in their April 1999 "Responsiveness Summary for the Royalton-Hartland School Yard Interim Corrective Measure," acknowledging in part that some of the assumptions used were "conservative."

Remediation projects conducted to date by FMC have been directed by the Agencies as ICMs and/or discussed and agreed to by the Agencies as “Early Actions” in order to demonstrate progress in remediation of off-site areas while performance of the RFI/CMS continues. It should also be noted that off-site soil remediation projects performed to date were conducted prior to completion of the CMS. Consequently, the scopes of work for those soil removals were conservatively determined to minimize the possibility that those remediated areas would require further remediation once the CMS was completed.

FAQ #3 – How are the Agencies considering human health risk associated with arsenic concentrations in soil?

FMC Comment on the Agencies’ Answer #3 – FMC respectfully disagrees with the Agencies’ statement that a theoretical excess cancer rate of one-in-one million (10^{-6}) is the “maximum cancer risk level allowed by New York State legislation.” As discussed in FMC’s Comment on the Agencies’ Answer #2, above, the New York State law referenced in the Agencies’ answer is part of the NYS Brownfield Cleanup Program, which is a voluntary program. For the reasons discussed above, the NYS Brownfield law is not applicable to FMC Middleport’s RCRA Corrective Action program and the Administrative Order on Consent under which this program is being conducted.

In addition, see above FMC Comment on the Agencies’ Answer #1 concerning the use of 20 ppm as the Middleport soil arsenic background criterion.

FMC believes that site-specific human health risks associated with arsenic levels in soils should be estimated using reasonable, health protective assumptions that take into account the real exposures at the particular site. The site-specific health risks should be compared to the USEPA non-cancer target risk level of 1.0 and the USEPA acceptable cancer risk range of 10^{-4} to 10^{-6} . In 2003 and early 2004, FMC proposed to the Agencies the performance of separate RFIs, site-specific risk assessments and CMSs for the following study areas: 1) Tributary One South of Pearson/Stone Roads & Culvert 105 North of the Canal; 2) North Railroad Property; and 3) Areas Potentially Affected by Historic Air Deposition. At that time, the Agencies advised that they did not agree with the concept of performing separate “area-specific” RFI/CMSs for the off-site study areas (on an “operable unit” approach) and informed FMC that site-specific risk assessments should be performed as part of the CMS in conjunction with the review of each identified corrective measure alternative. Accordingly, FMC intends to perform site-specific risk assessments to identify the remediation areas and to compare various corrective measures alternatives as part of the CMS of the off-site study areas. The ICM and Early Action projects that have been performed to date or that are currently underway have not included site-specific risk assessment evaluations. The implication in the Agencies’ answer to the contrary is simply incorrect.

FAQ #4 – Why were arsenic concentrations in soil above 20 ppm left on the Roy-Hart School property after the 1999 remediation and how is this different than the residential properties?

FMC Comment on the Agencies’ Answer #4 – As discussed in the above FMC Comment on the Agencies’ Answer #2, the USEPA performed a site-specific risk assessment in 1998 that evaluated all arsenic soil data available at that time from the Roy-Hart school property. According to the draft

report, the risk assessment evaluated both “Central Tendency Exposure” (CTE) scenarios and “Reasonable Maximum Exposure” (RME) scenarios. The risk estimates for the CTE scenarios used an average (arithmetic mean) of all surface soil data in calculating the exposure point concentration for the exposure area evaluated. FMC agrees with the Agencies that site-specific risk assessments should use the CTE approach that calculates and evaluates information using an arithmetic mean. The risk estimates for the RME scenarios were based on a 95% Upper Confidence Limit of the mean (95% UCL) of all surface soil data in calculating the exposure point concentration for the exposure area evaluated. The 95% UCL represents a 95% probability that the true average of all surface soil data is below the 95% UCL value. The 95% UCL value represents a conservative estimate of the arithmetic mean that accounts for a possibility that additional arsenic soil levels may increase the arithmetic mean. The Agencies evaluated potential human health risks associated with the arsenic soil levels in the surface soil outside of the ICM area where remediation would not occur pursuant to the ICM work plan. In the Agencies’ April 1999 Responsiveness Summary for the Roy-Hart School Yard ICM, the Agencies used the following arsenic levels in surface soils to evaluate the post-ICM health risks to Roy-Hart students:

Exposure Area (Excluding the 1999 Football Field/Track ICM Area)	CTE Scenario (Average Concentration)	RME Scenario (95% UCL)
Entire School Yard (Exposure Area A)	26.2 ppm	38.2 ppm
Behind High School (Exposure Area B)	21.9 ppm	32.2 ppm
Behind Elementary School (Exposure Area D)	28.5 ppm	44.9 ppm

Using the above arsenic levels, the Agencies determined that none of the school yard exposure areas exceeded the USEPA non-cancer threshold hazard index of 1.0 or the USEPA acceptable cancer risk range of 10^{-4} to 10^{-6} . As documented in the Agencies’ April 1999 Responsiveness Summary, the Agencies also compared the above average arsenic soil concentrations to the local background soil arsenic data available in 1999 and determined that the average levels were “*within the lower half of the 4.4 ppm to 56.1 ppm range of the local background data set. Therefore, the Agencies consider the “post-ICM” average arsenic levels in the school yard soils to be consistent with the arsenic levels of the local background data set...*”

FAQ #5 – How do the arsenic concentrations being used in the cleanup of other sites in the US, compare with those being used by New York State and in Middleport, and why are there differences?

FMC Comment on the Agencies’ Answer #5 – The statement that in "EPA Regions 8, 9 and 10 combined ... there were substantially more industrial decisions resulting in higher cleanup values ... at these sites" is confusing and factually incorrect. It is our understanding that a number of the sites in those regions where higher arsenic soil clean-up levels have been established did involve residential properties. Some examples of residential arsenic action levels selected in these and other USEPA regions are as follows:

Cleanup Site Name/Location	Residential Arsenic Soil Action Level	Year	Lead Environmental Agency	Notes
Anaconda, Montana	250 ppm (based on <i>average</i> soil arsenic level for a residential yard)	1996	USEPA Region 8	Site-specific risk based. May 2007 ATSDR Health Consultation report stated that 1) chronic exposure to soil at the residential cleanup level of 250 ppm of soil would not be expected to result in adverse health effects for resident children or adults, and 2) EPA's selected arsenic soil cleanup level of 250 ppm results in a calculated increased cancer risk of 8 in 100,000 (8×10^{-5}).
East Omaha, Nebraska	70 ppm (based on <i>average</i> soil arsenic level for a residential yard)	--	--	Site-specific risk based. March 2007 ATSDR Health Consultation report stated that "Arsenic levels above 70 ppm are considered elevated; exposure at these levels are a concern for some children and adults with long-term exposure to arsenic." ASTDR letter to residents stated that "[r]esidential yards with an average level of arsenic in soil above 70 parts per million (ppm) might be a health concern..."
Vasquez Boulevard/ Interstate 70 Superfund Site Denver, Colorado	70 ppm; 47 ppm for PICA children (based on the highest arsenic concentration from <i>composite</i> soil samples)	2003	USEPA Region 8	Site-specific risk based. The USEPA September 23, 2003 Record of Decision states that "[t]he action level for arsenic is exceeded when the highest arsenic concentration from three composite soil samples taken from the property is greater than 70 ppm."
Spring Valley Washington D.C.	20 ppm 43 ppm for tree root zone or other areas (based on <i>discrete</i> arsenic soil sample results)	2002	USEPA Region 3, D.C. Department of Health, and Army Corp of Engineers (ACE)	Included ability to retain trees. As stated in the ACE Resident's Guide for Spring Valley Soil Removal, "... although the cleanup goal is to remove arsenic-contaminated soil that exceeds 20 ppm, health officials agree that it is acceptable and still protective for soil below 43 ppm to remain in the root zones of trees or where access or other construction limitations make soil removal difficult or unsafe."

Cleanup Site Name/Location	Residential Arsenic Soil Action Level	Year	Lead Environmental Agency	Notes
El Paso County/Dona Ana County Metals El Paso, Texas	46 ppm	2003	USEPA Region 6, Texas Commission of Environmental Quality	Site-specific risk based. July 2003 ATSDR Health Consultation report stated that “the proposed cleanup level of 46 mg/kg for arsenic in surface soil at this site would pose no apparent public health hazard.”
Barber Orchard Site Waynesville, North Carolina	40 ppm	2004	USEPA Region 4	Site-specific risk based as presented in the September 24, 2004 Record of Decision.

Note: Additional soil arsenic cleanup levels are summarized in the Agency for Toxic Substances and Disease Registry (ATSDR) Health Consultation report entitled “Evaluation of Residential Soil Arsenic Action Level Anaconda Co. Smelter NPL Site, Anaconda, Deer Lodge County, Montana” (May 2007) and found at <http://www.atsdr.cdc.gov/hac/pha/HCPHA.asp?State=Montana>

FAQ #6 – Will a variety of arsenic cleanup objectives and remedial alternatives be evaluated, and how will community concerns (e.g., property values, trees, etc.) be considered during the remedy selection process?

FMC Comment on the Agencies’ Answer #6 – FMC welcomes the Agencies’ recognition that excavation is not the only appropriate corrective measure, and that other measures can be considered during the CMS process. FMC encourages this same flexibility for any additional ICMs or early actions.² In addition, the Agencies suggest that “tree preservation” could be part of the CMS. FMC submits that tree preservation can also be accommodated in the context of early actions, and that the issuance of letters with reservations or the declining altogether to issue a letter to a residential property owner who has not consented to have a mature, healthy tree removed, is wrong.

During the September 13th meeting with the Middleport Community Input Group (MCIG) FMC reviewed a proposed course of action that included completion of separate RFI report volumes and the performance of separate CMSs (and site-specific risk assessments for the corrective measure alternatives evaluated) for the 1) Areas Potentially Affected by Historic Air Deposition, 2) Tributary One south of Pearson Road, and 3) Culvert 105. The RFI and CMS for the Historic Air Deposition area would be completed first. While the Agencies did not accept this approach, and the concept of proceeding by operable units for the off-site areas, when FMC proposed it in 2003 and early 2004, and while the Agencies’ Answer #6 still refers to “a CMS,” the time required and the need to respond to

² In Answer #6, the Agencies characterize the soil remediations performed to date as those “required by the Agencies as in the case of the Roy-Hart School property or proposed by FMC as in the case of past and current residential remediations.” This is not entirely accurate. While FMC did initially propose the soil remediation work for the fourteen residential properties west of the FMC Plant site, that work was directed to be performed by the Agencies as an ICM. The current soil remediation work on the Park Avenue and Culvert 105 south of Sleeper Street residential properties has been performed as an “early action”, and not as an ICM directed by the Agencies.

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community concerns now warrant reconsideration. FMC will be discussing with the Agencies the process for completion of the RFI/CMS for the off-site study areas.

FMC will continue to involve the MCIG, affected property owners and community during the performance of the CMS. A public participation program for the CMS will be developed and reviewed with the MCIG and Agencies.

If there are any questions or if additional information is needed at this time, please contact me at (215) 299-6047 or at the above address.

Sincerely,



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