OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Public Liaison Report

Review of Environmental Concerns at McFarland, California

Report No. 2006-P-00041

September 28, 2006

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Abbreviations

ARARs	applicable, relevant, or appropriate requirements
ATSDR	Agency for Toxic Substances and Disease Registry
CIC	Community Involvement Coordinator
EPA	U.S. Environmental Protection Agency
FR	Federal Register
HOME	Healing Our Mother Earth
MCL	Maximum Contaminant Level
NCP	National Contingency Plan
OIG	Office of Inspector General
PRGs	preliminary remediation goals
ug/L	micrograms per liter

Photo caption: Residential yards in McFarland beside agricultural fields with spray-applied pesticides (EPA OIG photo).

U.S. Environmental Protection Agency
Office of Inspector General

2006-P-00041
September 28, 2006

At a Glance

Catalyst for Improving the Environment

Why We Did This Review

We conducted this review to evaluate issues and concerns raised by an environmental group and other concerned citizens regarding the potential for exposure to hazardous substances in McFarland, California. This case was transferred from the U.S. Environmental Protection Agency's (EPA's) former National Ombudsman in April 2002, when the EPA Administrator assigned the Ombudsman function to the Office of Inspector General.

Background

During the 1980s, residents of McFarland noticed health problems that they attributed to water, air, and soil contamination. A study by State and county officials concluded that McFarland had unusually high rates of cancer, but no causal association could be made between health data and the contaminants identified during sampling. EPA's National Ombudsman recommended that EPA conduct comprehensive environmental studies.

For further information, contact our Office of Congressional and Public Liaison at (202) 566-2391.

To view the full report, click on the following link:
www.epa.gov/oig/reports/2006/20060928-2006-P-00041.pdf

Review of Environmental Concerns at McFarland, California

What We Found

EPA developed preliminary remediation goals for McFarland using a lifetime residential exposure assumption of 30 years based on Agency Superfund guidance. We believe a 70-year exposure assumption may be more appropriate where there are multiple contaminants and multiple exposure pathways. We believe that this more accurately reflects the intent of the National Contingency Plan to be more protective under such environmental conditions.

EPA appears to have conducted air and soil sampling activities appropriately. However, when analyzing drinking water sampling results, Region 9 did not consider the synergistic effects of multiple contaminants and multiple exposure pathways due to limited available information on such effects. A new arsenic Maximum Contaminant Level was not effective until January 2006; thus, it is too early to determine whether the States are properly implementing it. The Region is helping States to acquire funding to install treatment systems and is conducting training on new treatment technologies to help them meet the new standard.

Region 9 exceeded requirements in its efforts to keep the McFarland community informed, but can take some actions to further strengthen community relations.

What We Recommend

We recommend that the Office of Research and Development identify and provide public access to sources of information on the toxicology of contaminant mixtures that may be found in drinking water, and continue to support research characterizing the joint toxic action of contaminants in drinking water. That Office generally agreed with the recommendations in our draft report, but suggested minor revisions, with which we generally concurred. We also make several suggestions for Region 9 to consider. The Region should provide an explanation for not using a 70-year lifetime exposure assumption when issuing preliminary remediation goals for specific sites, including McFarland. It should also provide an explanation for not using a lifetime excess cancer risk level of 1 per every 1,000,000 residents in setting preliminary remediation goals for water that could be used as a drinking water source where multiple contaminants are present.

Region 9 disagreed with our interpretation of the National Contingency Plan. We continue to believe a 70-year exposure assumption and a lifetime excess cancer risk of 1 per every 1,000,000 residents may be more appropriate where there are multiple contaminants and exposure pathways, such as at McFarland.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

September 28, 2006

MEMORANDUM

SUBJECT: Review of Environmental Concerns at McFarland, California
Report No. 2006-P-00041

TO: Wayne Nastri
Regional Administrator, Region 9

George M. Gray
Assistant Administrator for Research and Development

Attached is our final report on our review of complaints regarding environmental concerns at McFarland, California, conducted by the Office of the Inspector General (OIG). We undertook this work as a result of issues brought to the attention of the former U.S. Environmental Protection Agency (EPA) Ombudsman and, subsequently, to the OIG Office of Congressional and Public Liaison by residents of McFarland and environmental organizations.

This report contains findings and recommendations that describe needed improvements the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and the findings contained in this report do not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

On July 31, 2006, the OIG issued a draft report to EPA's Region 9 and the Office of Research and Development for review and comment. The offices provided a joint response on August 30, 2006. We have included the Agency's comments and our responses in Appendix A of this report.

The findings in this report are not binding in any enforcement proceeding brought by EPA or the Department of Justice under the Comprehensive Environmental Response, Compensation, and Liability Act to recover costs incurred not inconsistent with the National Contingency Plan.

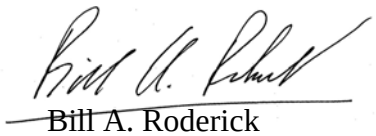
The estimated cost of this report – calculated by multiplying the project's staff days by the applicable daily full cost billing rates in effect at the time – is $299,002.

Action Required

In accordance with EPA Manual 2750, you are required to provide this office with a written response within 90 days of the final report date. You should include a corrective action plan for agreed upon actions, including milestone dates. We have no objections to the further release of this report to the public. This report will be available at http://www.epa.gov/oig.

If you or your staff have any questions, please contact me at 202-566-0847 or roderick.bill@epa.gov, or Paul McKechnie, Product Line Director for Public Liaison, at 617-918-1471 or mckechnie.paul@epa.gov.

Sincerely,



Bill A. Roderick
Acting Inspector General

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Chapter 1
Introduction

Purpose

The U.S. Environmental Protection Agency (EPA) Office of Inspector General (OIG) conducted a review of environmental concerns in McFarland, California, which were raised by an environmental group and other concerned citizens. These concerns involved potential exposure to hazardous substances in McFarland and any resulting public health problems.

In evaluating the concerns, we addressed the following questions:

1. Does EPA's risk assessment adequately address human health issues?

2. Were air, soil, and water sampling activities conducted appropriately?

3. Is the new arsenic Maximum Contaminant Level requirement being properly implemented?

4. Have EPA's public outreach activities at McFarland been effective?

This case was among those transferred from the former National Ombudsman in April 2002, when the EPA Administrator moved the Ombudsman function to the OIG to implement the recommendations in a General Accounting Office (now Government Accountability Office) report.

Background

McFarland is an agricultural community located 25 miles north of Bakersfield, California. The town has a population of about 10,000, and many residents work in agricultural activity, including crop production, chemical application, storage, and shipment of agricultural products. The town is surrounded by crop land, pastures, and orchards. The area was the site of an Army basic pilot training field during World War II.

Beginning in the 1980s, residents of McFarland noticed health problems that they attributed to contamination in the water, air, and soil. This prompted local activists, including the Healing Our Mother Earth (HOME) and Greenlaw environmental organizations, to draw the attention of government to these health issues.

The California Department of Health Services, in cooperation with the Kern County Health Department, conducted environmental sampling from 1985 through 1989, analyzing soils in the yards of residences where one or more family members had cancer, and comparing the results to soils in the yards of residences without cancer cases. EPA provided technical assistance to the California Department of Health Services for some of its tasks. Nitrates were found in some municipal wells. Arsenic, a known human carcinogen, though present in nearly all drinking water and soil samples, was discounted as a reason for illness because naturally occurring arsenic is commonly found in California soils. Analysis of aerial photographs did not reveal evidence of hazardous waste sites, and measurements of electromagnetic fields did not indicate unusually high levels of electromagnetic radiation. However, the epidemiological study concluded that the towns of McFarland, Fowler, and Rosamond had unusually high rates of cancer. The California Department of Health Services concluded that while the cancer cluster was real, no causal association could be made between the health data and the levels of toxic compounds identified by previous environmental sampling.

As a result of the activities of the HOME organization, the EPA National Ombudsman began investigating the issues in 1994. The McFarland case also drew attention from Congress. The National Ombudsman recommended that EPA Region 9 conduct comprehensive environmental investigations.

In 1995, residents of McFarland, supported by the HOME organization, petitioned EPA and the Agency for Toxic Substances and Disease Registry (ATSDR) to evaluate potential exposure to hazardous substances in their environment and any resulting public health problems. EPA was petitioned to conduct sampling and analysis activities for air, soil, and water. ATSDR was petitioned to conduct an immediate health consultation and investigation, as well as a comprehensive health assessment. In conducting the health assessment, ATSDR reviewed water and soil sampling data provided by EPA.

During the period 1997 through 2002, Region 9 conducted air, water, and soil sampling in the McFarland area. The results of a drinking water investigation at McFarland issued in June 2000 identified more than 60 chemicals in the drinking water, in concentrations that, with the exception of arsenic, were not – taken separately – of health concern. Naturally occurring arsenic was present in 90 percent of the samples. Region 9 issued a report on the latest round of air sampling in October 2004, concluding that the highest concentrations of arsenic and three other metals occurred during a dust storm in May 2002. The Region plans to issue final reports on the results of all sampling at McFarland in early 2007.

ATSDR's April 2001 Public Health Assessment concluded that:

> *… based on the available data, no adverse health effects would be expected from people coming into contact with soil or using the municipal water supply.*

The ATSDR assessment also found 17 different toxic substances and pesticides in soil and water, though these contaminants were present at levels that, taken separately, were not of health concern.

Scope and Methodology

We performed our review in accordance with *Government Auditing Standards*, issued by the Comptroller General of the United States. We conducted the review from September 29, 2004, through September 13, 2005. We issued an initial draft report on December 23, 2005, and issued a revised draft report on July 31, 2006, as requested by the Agency. We did not review the system of internal controls due to the limited scope of our evaluation and the fact that such a review was not relevant to our objectives.

We reviewed environmental sampling reports and health studies for McFarland for the period 1985 through August 2005. To accomplish our objectives, we reviewed the petitions submitted by the HOME environmental organization to EPA and ATSDR. We reviewed criteria in the National Contingency Plan (NCP) and compared them to Region 9's preliminary remediation goals (PRGs) for McFarland. We examined the results of air, soil, and water sampling conducted at McFarland. We interviewed the organizer of the HOME environmental group to discuss past and present concerns. We interviewed McFarland residents, school officials, city officials, and a physician at the local medical clinic. We met with EPA regional staff to discuss their actions and to obtain their responses to a list of questions relating to our review.

There were no prior EPA OIG or Government Accountability Office reviews regarding environmental concerns at McFarland that required followup.

Chapter 2
Preliminary Remediation Goals Based on 30-Year Lifetime Exposure Assumption

Region 9 based the PRGs it developed for McFarland on a lifetime residential exposure assumption of 30 years as indicated in the Agency's Risk Assessment Guidance for Superfund. We believe that a 70-year exposure assumption may be more appropriate where there are multiple contaminants and exposure pathways such as at McFarland, and more accurately reflects the intent of the NCP to be more protective under such environmental conditions. EPA's risk assessment guidance also indicates that a 70-year exposure assumption may be more appropriate in some cases.

Preliminary Remediation Goals

Region 9 developed a set of PRGs for McFarland that it used to analyze sample results to determine the health risks to residents from exposure to contaminants in the water and soil. The Region developed the PRGs because many toxic chemicals that it sampled for had no mandatory exposure standards. There are no established standards, or applicable, relevant, or appropriate requirements (ARARs)[1] for many of the more than 60 contaminants present in the drinking water at McFarland. EPA's January 2001 Drinking Water Investigation Report indicated that PRGs combine a compound's current EPA toxicity values with standard exposure factors to estimate contaminant concentrations in environmental media. The report concluded that levels of chemicals or compounds that are at or below PRGs did not pose an appreciable health risk to those persons using McFarland's drinking water.

PRGs Assume 30-Year Lifetime Exposure

Although the Region did not consider McFarland to be a Superfund site, it conducted its environmental assessment of McFarland under Superfund as the lead program. The Region assessed McFarland using the NCP as one policy framework, along with EPA air and water quality standards.

The NCP requires that for known or suspected carcinogens the acceptable exposure levels in drinking water are no worse than 10^{-4} risk levels (1 per every 10,000 residents), but requires that a risk level of 10^{-6} (1 per every 1,000,000

[1] Section 121(d) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 requires that on-site remediation actions attain or waive Federal environmental ARARs, or more stringent State environmental ARARs, upon completion of remediation actions. The NCP also requires compliance with ARARs during remedial and removal actions to the extent practicable.

residents) be used as a point of departure in setting remediation goals when there are multiple contaminants or multiple exposure pathways. The following excerpts from the preamble of the NCP, as published in the Federal Register (FR), help explain the mandatory requirement in the regulation for development of remediation plans:

> *EPA will set remediation goals for total risk due to carcinogens that represent an excess upper bound lifetime cancer risk to an individual to between 10^{-4} to 10^{-6} lifetime excess cancer risk. A cancer risk of 10^{-6} will serve as the point of departure for these remediation goals.* (55 FR 8713, March 8, 1990)
>
> *EPA's preference, all things being equal, is to select remedies that are at the more protective end of the risk range. Therefore, when developing its preliminary remediation goals, EPA uses 10^{-6} as a point of departure….* (55 FR 8716, March 8, 1990)
>
> *EPA believes it is necessary to explain how it intends the point of departure to be used. Where the aggregate risk of contaminants based on existing ARARs exceeds 10^{-4} or where the remediation goals are not determined by ARARs, EPA uses 10^{-6} as a point of departure for establishing preliminary remediation goals. This means that a cumulative risk level of 10^{-6} is used as the starting point (or initial protectiveness goal) for determining the most appropriate risk level that alternatives should be designed to attain.* (55 FR 8718, March 8, 1990)
>
> *By using 10^{-6} as the point of departure, EPA intends that there be a preference for setting remediation goals at the more protective end of the range, other things being equal.* (55 FR 8719, March 8, 1990)

The NCP refers to "excess upper bound lifetime cancer risk:"

> *For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response.* (Title 40 Code of Federal Regulations 300.430(e)(2)(i)(A)(2))

In developing the PRGs for McFarland, Region 9 used the Agency's Risk Assessment Guidance for Superfund, which generally recommends a 30-year residential exposure assumption for determining reasonable maximum exposure at a site. The 30-year assumption was based on the results of a survey conducted by the Bureau of the Census in 1983 on how long families had been living in their existing residences.

Other interpretations of what is meant by cancer risks from lifetime exposure, however, differ from the Agency's 30-year exposure assumption:

- The reference text, *Casarett and Doull's Toxicology – The Basic Science of Poisons* (Fifth Edition, 1996), defines lifetime exposure as exposure for 365 days per year for a 70-year lifetime.

- ATSDR defines lifetime exposure as being exposed to a substance every day for 70 years.

- EPA's Integrated Risk Information System refers to 70 years for lifetime exposure.

- EPA's Office of Water and Office of Air and Radiation, as well as the Integrated Risk Information System, use defaults to quantify the risks associated with exposure to contaminants that are consistent with the preamble of the NCP.

- EPA's Risk Assessment Guidance for Superfund (Exhibits 6-11 through 6-15) defines lifetime, by convention, as 70 years.

- EPA's Risk Assessment Guidance for Superfund, Volume I – Human Health Evaluation Manual (Part C, Risk Evaluation of Remedial Alternatives) defines the number of days in a lifetime as 25,600 days, which is 70 years.

- EPA's Risk Assessment Guidance for Superfund, Volume I – Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals) indicates an averaging time of 70 years for determining cancer risk.

The PRGs for McFarland do not appear to meet the NCP requirements for more protective 10^{-6} risk levels when there are multiple contaminants or multiple exposure pathways. Region 9 staff, applying the Agency's risk assessment criteria, used a residential exposure assumption of 350 days per year for 30 years, which differs from the interpretations of lifetime exposure cited above. The interpretations above define lifetime exposure as exposure for 365 days per year for 70 years, which we believe more accurately reflects the intent of the NCP. The areas investigated in McFarland included many residences for which the exposure is constant for as long as the home is occupied. Children and seniors, some of whom are ill, live in these residences.

EPA's risk assessment guidance states that there may be some cases where a 70-year lifetime exposure assumption may be more appropriate to use than a 30-year exposure assumption. However, the guidance does not define when the

70-year exposure assumption should be used, aside from consulting with the Remedial Project Manager regarding appropriate exposure durations.

Another significant factor is the potential cumulative effects of multiple contaminants. The OIG has not found any research dealing specifically with the cumulative effects of the contaminants that exist in McFarland drinking water. However, we have identified the following examples of research on the synergistic effects of multiple contaminants:

> *One of the most studied examples is the interaction between occupational exposure to asbestos fibers and cigarette smoking. In the study by Hammond et al. (1979), relative risks of about 5, 11, and 53 were noted for nonsmokers with occupational exposures to asbestos, smokers with no occupational exposure to asbestos, and smokers with occupational exposure to asbestos, respectively… As discussed by Steenland and Thun (1986), synergistic departures from an additive risk model have important public health consequences in that eliminating exposure to one agent can result in a greater reduction in risk than if no synergistic interaction occurred.* (Technical Support Document on Risk Assessment of Chemical Mixtures, EPA/600/8-90/064, November 1988, pp. 2-25, 2-26)

> *A synergistic effect occurs when the combined effects of two chemicals are much greater than the sum of the effects of each agent given alone. For example, both carbon tetrachloride and ethanol are hepatotoxic compounds, but together they produce much more liver injury than the mathematical sum of their individual effects on the liver would suggest… Isopropanol, for example, is not hepatotoxic, but when it is administered in addition to carbon tetrachloride, the hepatotoxicity of carbon tetrachloride is much greater than that when it is given alone.* (Casarett and Doull's Toxicology, The Basic Science of Poisons, Fifth edition, 1996, McGraw Hill, p. 18)

A study published by the University of Iowa in 2002 concluded that the synergy of simultaneous dust and ammonia exposures in the working environment for poultry production workers raised the question of redefining exposure limits for organic dust and ammonia when workers are exposed simultaneously to these substances. The study concluded that lack of control of both of these contaminants would increase the risk of respiratory dysfunction to all exposed to this environment, including production workers and veterinarians.[2]

So clearly, the existing science indicates situations of multiple contaminants have more serious effects. We believe this lack of data is reason to be more, rather than less, protective when assessing the risk of multiple contaminants at a site.

[2] *Synergistic Effects of Dust and Ammonia on the Occupational Health Effects of Poultry Production Workers*, K.J. Donham, D. Cumro, S. Reynolds, Department of Occupational and Environmental Health, College of Public Health, University of Iowa, Iowa City, in Agromedicine, 2002, 8(2):57-76

Conclusions

Although Region 9 developed the PRGs for McFarland applying existing Agency Superfund guidance and the NCP, we consider the PRGs to be less stringent than NCP requirements for 10^{-6} risk levels where there are multiple contaminants and exposure pathways, such as at McFarland. The PRGs are based on a lifetime residential exposure assumption of 30 years, although alternative interpretations of lifetime exposure indicate an exposure of 70 years may be more appropriate. We believe the 70-year exposure assumption, when there are multiple contaminants and exposure pathways, more accurately reflects the intent of the NCP to be more rather than less protective under such environmental conditions. EPA's guidance also notes that a 70-year exposure assumption may be more appropriate than a 30-year assumption in some cases, but does not clearly define when to use the 70-year assumption.

We suggest that the Region, as a good management practice, provide an explanation for not using a 70-year lifetime exposure assumption when issuing the PRGs for specific sites, including McFarland.

Agency Response and OIG Comment

Region 9 disagreed with our conclusion that a 70-year exposure assumption should be used when there are multiple contaminants and exposure pathways at a site, but provided no new justification for this view. For reasons already stated, we stand by our conclusion regarding lifetime exposure. The Region based the PRGs it developed for McFarland on a lifetime residential exposure assumption of 30 years as indicated in the Agency's Risk Assessment Guidance for Superfund, and believes this is consistent with the NCP.

The NCP, however, states that:

> *…acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} to 10^{-6} using information on the relationship between dose and response.* (55 FR 8848, March 8, 1990)

As further support for our position, one other EPA region has interpreted lifetime exposure similar to the OIG's interpretation. In a September 1993 amendment to the Record of Decision for the McAdoo Associates Superfund site in Pennsylvania, Region 3 indicated that lifetime exposure was equivalent to an exposure of 70 years. In addition, when commenting on a risk assessment for the Enterprise Avenue Superfund site in Philadelphia, Pennsylvania, in April 1984, a Region 3 toxicologist noted that a risk level of 10^{-6} was more appropriate than 10^{-5} considering past EPA actions and current Agency thinking in estimating risks acceptable to the public.

The full text of the Agency's response, along with additional OIG comments, are in Appendix A.

Chapter 3
Air and Soil Sampling Conducted Appropriately; Water Analyses Did Not Consider Interactions of Contaminants

EPA appears to have conducted air and soil sampling activities at McFarland appropriately. However, when evaluating the results of drinking water sampling, Region 9 did not consider the synergistic or additive effects of multiple contaminants, due to limited available information on these effects. Because a new Maximum Contaminant Level (MCL) for arsenic in drinking water became effective in January 2006, it is too early to determine whether the States are properly implementing it.

Synergistic Effects of Multiple Contaminants in Drinking Water

The NCP requires that, for known or suspected carcinogens, the acceptable exposure levels in drinking water are no worse than 10^{-4} (1 per every 10,000 residents). When the ARARs are unavailable or not sufficiently protective, the NCP requires the use of 10^{-6} risk levels (1 per every 1,000,000 residents) to be used as a point of departure in setting remediation goals where there are multiple contaminants or multiple exposure pathways, to provide an adequate margin of safety. This is because the interactions or synergistic effects among contaminants are unknown since limited research has been done by EPA, other agencies, private industry, and academia to investigate the synergistic or additive effects of multiple contaminants.

The NCP requires that:

> *For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response. The 10^{-6} risk level shall be used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure.* (Title 40 Code of Federal Regulations 300.430(e)(2)(i)(A)(2))

As explained in the preamble:

> *In cases involving multiple contaminants or pathways where attainment of chemical-specific ARARs will result in cumulative risks in excess of 10^{-4}, criteria in paragraph (e)(2)(i)(A) of this section may also be considered when determining the cleanup level to be attained.* (55 FR 8848, March 8, 1990)

Based on the results of an EPA investigation of McFarland drinking water,[3] there are 61 contaminants present in the drinking water:

- 22 metals
- 14 synthetic organics
- 13 disinfection by-products
- 5 volatile organics
- 4 other inorganics
- 3 radionuclides

Water providers are required to meet drinking water standards (ARARs) prior to serving water to the public. One contaminant (di[2-ethylhexyl]phthalate) was present in concentrations above its ARAR level. When questioned, Regional staff provided additional information about sampling and analysis of di[2-ethylhexyl]phthalate. Regional staff indicated that the higher analysis results were due to laboratory error. In reviewing the data, we found a discrepancy in the number of samples taken (30 in the summary instead of 34 in the Appendices to the same document). We also found that data from May 30, 2000 was being used to correct summary data dated June 1, 2000. Consequently, we can draw no firm conclusion about the concentrations of di[2-ethylhexyl]phthalate due to discrepancies in the data provided by the Region.

Another contaminant (radon 222) was present right at its ARAR level. While arsenic levels did not exceed the MCL of 50 micrograms per liter (ug/L) in effect at the time of sampling, the levels found exceed the current MCL of 10 ug/L. Four contaminants (arsenic, radon, bromodichloromethane, and benzo(a)pyrene) exceeded the ATSDR Cancer Risk Evaluation Guides, which are conservative, preliminary screening devices based on the same cancer risk assumptions that EPA uses. Taken on an additive basis, we believe the cumulative risk for the contaminants found in McFarland drinking water during the study exceeds the 1×10^{-4} risk allowed under the NCP.

[3] *Phase 2 McFarland Drinking Water Investigation Results Summary*, June 1, 2000.

New MCL for Arsenic

A new MCL for arsenic in drinking water became effective in January 2006. The new MCL requires that the level of arsenic in drinking water not exceed 10 ug/L, compared to the previous MCL of 50 ug/L. For the new arsenic MCL, water providers have a compliance period to meet the new standard. It is too early to determine whether the States are properly implementing the new MCL. EPA is still in the process of determining how the States will meet the new standard. Region 9 noted that the California Department of Health Services will be collecting data and is responsible for ensuring that the State implements the new MCL standard. The Region indicated that its Water Program Office had been helping States to acquire funding to install treatment systems and had conducted training sessions and seminars on new treatment technologies to help them meet the new MCL requirement.

Air and Soil Sampling Activities Appear to be Appropriate

The air and soil sampling activities performed by EPA at McFarland appear to have been conducted appropriately. The number and locations of samples taken and the methods used appeared to be adequate and appropriate.

EPA indicated it had conducted four air sampling events over a period of about 1 year using about 20 air monitoring stations. The Agency sampled during the seasons when pesticides were most likely to be applied at surrounding farms in the area. EPA placed some monitoring stations near local schools to measure potential exposure for children, a more sensitive population group. The Agency examined Pesticide Use Reports for the period 1996-1999 for an area of a 5-mile radius around McFarland as part of its air sampling efforts.

For soil sampling, EPA indicated that it had sampled soil from four schools, two parks, six commercial/industrial facilities, eight residences, and the drainage basin in the northeast section of town near a closed well, during two sampling phases conducted in February 1999 and October 2000. EPA staff indicated that they had tested the soil for about 200 different chemicals. The Agency did not find any substances that would pose a significant health risk and noted that most substances found were below PRGs.

Conclusions

Region 9 appeared to have appropriately conducted air and soil sampling activities at McFarland. However, the Region did not factor in the interactions and potential synergistic effects of multiple contaminants when evaluating McFarland drinking water samples. It is too early to determine whether the States in Region 9 are properly applying the new MCL, since it became effective in January 2006.

Recommendations

We recommend that the Assistant Administrator for Research and Development:

3-1 Identify and provide access on the publicly available EPA/Office of Research and Development Website to currently available sources of information on the toxicology of contaminant mixtures that may be found in drinking water.

3-2 Continue support for research characterizing the joint toxic action (such as additivity, synergism, or antagonism) of contaminants in drinking water.

Until the synergistic effects at multiple contaminant sites have been studied and quantified, we suggest that Region 9 explain why it is not using a 10^{-6} upper bound lifetime excess cancer risk in setting PRGs for McFarland for water that could be used as a drinking water source where multiple contaminants are present.

Agency Response and OIG Comment

The Office of Research and Development generally agreed with Recommendations 3-1 and 3-2 in our draft report, but suggested some minor revisions. We considered the suggested revisions and modified Recommendation 3-2 accordingly. We revised Recommendation 3-1 based on the Office of Research and Development's suggested changes, but added a phrase for providing electronic access to the information.

Region 9 disagreed that the NCP requires a 10^{-6} level PRG whenever there are multiple contaminants or that synergistic effects must be considered in all cases where multiple contaminants are present. The Region indicated that the presence of multiple contaminants does not, in itself, demonstrate that ARARs are non-protective. Synergistic, antagonistic, and additive effects are an emerging science for which few reliable data are available or demonstrative of non-protectiveness.

We agree with the Region that "synergistic, antagonistic, and additive effects are an emerging science for which few data are available." We believe this lack of data is reason to be more, rather than less, protective when assessing the risk of multiple contaminants at a site. The NCP indicates that:

> *EPA's preference, all things being equal, is to select remedies that are on the more protective end of the risk range.* (55 FR 8716, March 8, 1990).

In addition, the NCP states that:

> *Where ARARs do not exist, or where the baseline risk assessment indicates that cumulative risks – due to additive or synergistic effects from multiple contaminants or multiple exposure pathways – make ARARs non-*

> *protective, EPA will modify preliminary remediation goals, as appropriate, to be protective of human health and the environment. For cumulative risks due to non-carcinogens, EPA will set the remediation goals at levels for individual chemicals such that the cumulative effects of exposure to multiple chemicals will not result in adverse health effects.* (55 FR 8713, March 8, 1990).

There are no ARARs for some of the chemicals present at McFarland. In addition, there are multiple contaminants and multiple exposure pathways. The Region admits that there is insufficient data to assess additive or synergistic effects of the chemicals in the McFarland drinking water.

The full text of the Agency's response, along with additional OIG comments, are in Appendix A.

Chapter 4
Efforts Made to Inform Community But Mailing List Needs to be Updated

Region 9 exceeded Superfund program requirements in its efforts to keep the local community informed at McFarland. However, the Region should update the current mailing list for McFarland residents and businesses, since the list is not completely accurate. As a result, not all residents received fact sheets mailed out by the Region or received notice of EPA open houses at McFarland where sampling results were discussed.

Public Outreach Activities Exceeded Requirements

In discussions with Region 9, the prior Community Involvement Coordinator (CIC) for the site noted that the Region followed a Superfund approach to community relations activities at the site, although the Region was not legally required to do so because McFarland is not classified as a Superfund site. The CIC indicated that she met with many local residents to discuss their concerns, and mailed out informational fact sheets regarding plans for environmental sampling and the results of sampling. The Region prepared fact sheets in Spanish as well as English, since a large percentage of McFarland residents are Spanish-speaking. The CIC said that the Region distributed the first fact sheet to the McFarland community in August 1996. Region 9 issued the most recent fact sheets regarding plans for and the results of air sampling in July 2004 and October 2004. The CIC noted that EPA established information repositories at local schools and libraries in McFarland and supplied them with fact sheets. The Region is currently working on the *McFarland Outdoor Air Investigation Report*, the *McFarland Soil Phase II Investigation Report*, and the McFarland Project report entitled *A Summary of Findings in the Water, Soil, and Outdoor Air Investigations.* Region 9 expects to finalize these three reports in 2007.

Mailing List Needs to be Updated

The current mailing list for McFarland needs to be updated. The mailing list contains approximately 2,380 addresses. However, of these, only about 1,100 included the names of residents or businesses. The remainder of the list did not identify residential or business names and only included post office box numbers. In a random sample of 70 residents included on the list, there were 7 (10 percent) incorrect addresses for the residents listed. In addition, 6 of 12 individuals we interviewed during our field visit to McFarland indicated they had not received official notification of EPA's most recent open house, which occurred on November 8, 2004. Those we interviewed included residents, school officials, and medical clinic staff.

Region 9 did not effectively update the mailing list for McFarland because the Region considered its existing list to be relatively accurate, although the CIC acknowledged that the population at McFarland had increased since the Region originally obtained the mailing list from a contractor around 1995. The CIC indicated she had met with many people in the community and asked them if any other individuals should be added to the mailing list. The CIC said she would add the additional names and addresses provided by community members to the list. The Remedial Project Manager for the site noted the Region did not receive many return mailings when they mailed fact sheets or other information to the community.

EPA's NCP requires that community relations personnel ensure that all appropriate public and private interests are kept informed, and that their concerns be considered throughout a response. Because the mailing list has not been kept up to date, not all residents have been provided fact sheets or informed of EPA's open houses and public meetings. To further strengthen EPA's community relations efforts, the Region should consider publicizing future open houses or public meetings through local media outlets.

Conclusions

Region 9 made efforts to keep the McFarland community informed of environmental sampling plans and results. We compliment the Region for conducting community relations at McFarland and treating this responsibility as if it were associated with a Superfund site.

Considering that the Region will be completing three additional reports in 2007 on environmental investigations at McFarland, an accurate, up-to-date mailing list would help ensure that all members of the community receive fact sheets and notice regarding the availability of the reports, and would strengthen EPA community relations at the site. Public outreach could also be strengthened by publicizing notices of future public meetings and open houses through the local media. Therefore, we suggest that Region 9 update the mailing list for McFarland for future communications and outreach to the community, and for providing notice of any future public meetings. In addition, the Region should consider publicizing notices of future public meetings through local media outlets to supplement the regional mailings.

Agency Response and OIG Comment

Although Region 9 did not address this suggestion in its response to our revised draft report, in its response to our initial draft report issued on December 23, 2005, Region 9 indicated it would update the mailing list for McFarland for future communications and outreach to the community. The Region planned to continue publicizing notices of future public meetings through local newspapers to

supplement the regional mailings. The OIG concurs with the Region's planned actions.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Claimed Amount	Agreed To Amount
3-1	13	Identify and provide access on the publicly available EPA/Office of Research and Development Website to currently available sources of information on the toxicology of contaminant mixtures that may be found in drinking water.	O	Assistant Administrator for Research and Development	Ongoing		
3-2	13	Continue support for research characterizing the joint toxic action (such as additivity, synergism, or antagonism) of contaminants in drinking water.	O	Assistant Administrator for Research and Development	Ongoing		

[1] O = recommendation is open with agreed-to corrective actions pending
C = recommendation is closed with all agreed-to actions completed
U = recommendation is undecided with resolution efforts in progress

Appendix A

Agency Response to Draft Report and OIG Comments

MEMORANDUM

SUBJECT: Draft Public Liaison Report:
Review of Environmental Concerns at McFarland, California
Assignment No. 2004-01495

FROM: Jane Diamond
Assistant Regional Administrator
Management and Technical Services Division

TO: Paul D. McKechnie
Director of Public Liaison
Office of the Inspector General

Thank you for the opportunity to review the draft report titled, *Draft Public Liaison Report: Review of Environmental Concerns at McFarland, California,* sent to Region 9 for comment on July 31, 2006. Region 9 appreciated the opportunity to respond to the previous draft report dated December 23, 2005, as well as the two Position Papers sent to Region 9 on May 16, 2006.

Region 9 still has concerns regarding the draft report, and we are providing the attached input to correct a number of factual inaccuracies. Moreover, some of the recommendations in the draft report are inconsistent with, and may have substantial implications on, long-established national Superfund policy and guidance.

As you know, Region 9 has invested years evaluating the environmental concerns of the McFarland community. While multiple government agencies have studied the community, EPA has performed the most extensive investigation to date. To sustain the trust and credibility the Agency has established with the community, it is very important that we convey accurate information.

Please feel free to contact me at (415) 972-3275 or Rich Hennecke, Regional Audit Follow-up Coordinator, at (415) 972-3760.

Attachments

Attachment 1: EPA Region 9 Response to OIG Draft Report
Attachment 2: EPA Office of Research and Development Response to OIG Draft Report

ATTACHMENT I
EPA REGION 9 RESPONSE TO OIG DRAFT REPORT ON MCFARLAND

I. INTRODUCTION

On July 31, 2006, the United States Environmental Protection Agency ("U.S. EPA") received the Office of the Inspector General ("OIG") Public Liaison draft report entitled, *Review of Environmental Concerns at McFarland, California, July 31, 2006* ("OIG draft report"). In accordance with EPA Manual 2750, EPA Region 9 is required to provide a written response to the findings and recommendations of the OIG draft report within 30 days of the report. The Region 9 response addresses the factual accuracy of the draft report and responds to the OIG conclusions and recommendations to Region 9. Region 9's response also includes as an attachment a response by the Office of Research and Development ("ORD") to OIG recommendations 3.1 and 3.2.

A. Background

In 1995, several McFarland community members petitioned U.S. EPA, under the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA"), 42 U.S.C. § 9601 et. seq., also known as the Superfund law, and Executive Order 12898, entitled *"Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations"* (February 11, 1994), for an investigation of the environment in the City of McFarland, California. Among other items, the petition cited a continuing childhood cancer cluster and various other health concerns. The community requested an environmental investigation to determine if McFarland residents were at significant risk for adverse health effects due to exposure to chemicals that may have been released to the drinking water, soil, or air in their environment.

In response, Region 9 formed a cross-programmatic McFarland Team with the goal of performing an assessment of current environmental conditions in the community. The objective of the McFarland investigation was to evaluate the current environmental conditions and potential chemical exposures via drinking water, soil, and outdoor air at the time of sampling, and determine if there were levels of substances that could pose a significant health risk. Region 9 explained to the community that the goal of the project was not to determine the cause of the cancer cases or any other existing health conditions in the community. Past environmental conditions, which could have contributed to the cancer cases or other health effects, may no longer be present or may have changed and could not be reconstructed.

B. Region 9 Approach to the McFarland Environmental Investigation

McFarland is not listed on the National Priorities List ("NPL") and is not similar to a typical NPL site where EPA is investigating an uncontrolled release of specific contaminants from a single facility. EPA has not issued guidance on environmental investigations or risk assessment specifically addressing the type of comprehensive community-wide environmental assessment undertaken at McFarland. In the absence of such specific guidance, Region 9, after consultation with the Office of Solid Waste and Emergency Response ("OSWER"), Office of Drinking Water

("ODW"), Office of Air and Radiation ("OAR"), Office of Prevention, Pesticides and Toxic Substances ("OPPTS"), and ORD, chose to generally follow the remedial investigation and risk assessment guidance developed for use in the Superfund program. In particular, EPA Risk Assessment Guidance for Superfund ("RAGS")[4], which incorporates conservative exposure assumptions, was used. However, since this was a cross-programmatic investigation involving also the Air and Drinking Water programs, the Region drew on other appropriate guidance and source material as the investigation progressed.

The McFarland investigation has been one of the most thorough community-wide environmental investigations to date anywhere in the country. In some ways, the investigation has been more rigorous than an NPL site investigation because such investigations typically focus on releases of specific chemicals of concern at a single facility. The McFarland investigation sought to assess more than: 300 substances in drinking water, 200 substances in soil, 140 substances in outdoor air, and 100 substances in indoor dust. In the course of the investigation, over a five-year period, Region 9 collected more than: 900 outdoor air samples, 1,000 water samples, 350 soil samples and a limited number of indoor dust samples. The measured chemical concentrations were a combination of contributions from all sources, both natural and anthropogenic, over a broad geographic area encompassing the entire City of McFarland. Region 9 issued five Sampling and Analysis Plans[5] ("SAPs") and six Results Summary Reports: three for the Drinking Water Investigation, two for the Soil Investigation and one for the Outdoor Air Investigation.

To address community members' concerns and keep them informed, Region 9 issued a Community Involvement Plan ("CIP") and published seventeen newsletters and fact sheets.[6] Fact sheets were placed at the McFarland repositories[7] and also mailed to the addresses on the McFarland mailing list. Region 9 also conducted nine public meetings and extensive door to door community outreach. Region 9 is working currently on the *McFarland Outdoor Air Investigation Report*, the *McFarland Soil Phase II Investigation Report*, and the McFarland Project report titled *A Summary of Findings in the Water, Soil, and Outdoor Air Investigations.*[8] Region 9 expects to finalize these three reports in 2007.

[4] RAGS Volume I: Human Health Evaluation Manual, Part A, Interim Final, December 1989, Volume I: Development of Risk-based Preliminary Remediation Goals, Part B, Interim, December 1991.
[5] Sampling and Analysis Plan refers to a Field Sampling Plan and a Quality Assurance Project Plan.
[6] As part of EPA's press statements, fact sheets are faxed to the local media, before public meetings are held in McFarland.
[7] McFarland repositories: Kern County Public Library, McFarland Branch, 500 Kern Avenue, McFarland, CA 93250; Beale Memorial Library, Local History Room, 701 Truxten Avenue, Bakersfield, CA 93301; Superfund Records Center, EPA Region 9, 95 Hawthorne Street, Suite 403S San Francisco, CA 94105.
[8] Results summary reports for the three investigations were published.

C. EPA Evaluation of the McFarland Investigation Results

Results of the McFarland investigation were evaluated against existing federal and state environmental standards (e.g., drinking water Maximum Contaminant Levels ("MCLs") and National Ambient Air Quality Standards ("NAAQS"). Where enforceable standards were not available (e.g., unregulated chemicals in drinking water, most soil analytes, and many air analytes), results were screened against health-based screening levels ("HBSLs").[9] The primary HBSLs used for screening were Preliminary Remediation Goals ("PRGs") developed following Superfund risk assessment guidelines.

Where available and applicable, existing Region 9 PRGs from the Region 9 1999 PRG Table were used for the McFarland project. There were cases where Region 9 PRGs were not available, or where newer toxicity data on pesticides were available from OPPTS. For these cases, "McFarland PRGs" were developed specifically for the project, in accordance with the 1999 Region 9 technical support document for PRGs. The McFarland PRGs were based on either a 30-year residential exposure scenario (which assumes 24-hour exposure, 350 days per year) or, where applicable, a 25-year occupational exposure scenario (assuming 8-hour exposure, 250 days per year).

Consistent with Superfund risk assessment guidelines, the PRGs in most cases were chemical concentrations in soil, drinking water, or outdoor air which correspond to a 10^{-6} excess lifetime cancer risk for carcinogens or to daily exposures corresponding to the reference dose for non-carcinogenic chemicals. For evaluation of chemicals in drinking water, Region 9 used the MCLs, which are the enforceable standards and would constitute the Applicable or Relevant and Appropriate ("ARAR") standards under Section 121(d) of CERCLA, 42 U.S.C.§9621(d).

The following sections explain how these risk assessment tools were applied to each media investigation.

> **1. Soil Investigation:** Region 9 compared the results of soil tests from residences and public areas (e.g., schools and parks) to residential soil PRGs. The results of soil tests from certain industrial facilities (e.g., Elmo Highway Complex, cotton gins, and Garza Service Station) were compared to industrial soil PRGs. For the industrial facilities, as an added level of assurance, it was also noted whether the levels of substances in soil were above or below residential PRGs. See *McFarland Soil Investigation Phase 1 Summary Report ("Phase 1"), Volume 1, August 2000, pp. 4-4*.
>
> In accordance with EPA standard practice, the presence of substances at levels greater than their respective screening levels was interpreted as an indication that additional evaluation was warranted to determine if those substances could pose a significant health risk to human health. For the McFarland soil investigation, this additional evaluation initially took two forms: 1) comparison with the typical background levels, and 2) further sampling at some locations to confirm Phase 1 results. (See *McFarland Soil Investigation Phase 1 Summary Report ("Phase 1"), Volume 1, August 2000, pp. 4-3 & 4-4*).

[9] HBSLs include screening levels such as PRGs, Health Advisories and California Action Levels.

2. Water Investigation: Substances were screened against federal or state MCLs, the enforceable drinking water standards established under the Safe Drinking Water Act.[10] Two types of drinking water standards were considered: 1) Federal Primary MCLs set by U.S. EPA, and 2) California Primary MCLs ("CA MCLs") set by the California EPA; the more stringent of the two was used at McFarland. Three types of risk-based screening levels were used for those compounds that did not have applicable drinking water standards; these were 1) Drinking Water Health Advisories ("HAs") set by U.S. EPA, 2) California Drinking Water Action Levels ("CAAL") set by the California EPA, and 3) PRGs.

3. Outdoor Air Investigation: EPA Region 9 compared the results to residential air HBSLs based on a 30-year exposure scenario or, where applicable, to the federal or state Ambient Air Quality Standards.

D. Arsenic in Drinking Water

Arsenic is a naturally occurring element found in the environment. Arsenic is found in both surface water and groundwater and is present in many groundwater sources in certain parts of the country, especially in parts of the western United States. The arsenic levels observed in McFarland's drinking water system were 0.48 - 18.2 ug/l. At the time the McFarland water investigation was conducted, the MCL for arsenic was 50 ug/l. Recently, this standard was changed to 10 ug/l.[11]

The U.S. Geological Service ("USGS") has surveyed public water systems in the United States and published statistics on arsenic levels in the public water supply.[12] The USGS study concluded that the highest levels of arsenic in drinking water systems are found in the western United States and that 13.6% of all public water systems have arsenic concentrations exceeding 5 ug/l, 7.6% have concentrations exceeding 10 ug/l, and 3.1% have concentrations exceeding 20 ug/l. The study indicated that the lower San Joaquin Valley, where McFarland is located, is one of many areas in the western United States where 10% or more of groundwater samples can be expected to have an arsenic level greater than 10 ug/l and that some areas of the lower San Joaquin Valley have groundwater levels greater than 50 ug/l. Thus, levels of arsenic in McFarland groundwater are comparable to natural background levels in much of the western United States and do not represent a distinguishing factor in the McFarland environment.

Region 9 anticipates that the local McFarland water system will take steps to bring the drinking water within acceptable exposures[13] if it intends to continue serving it to the public. The Water

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[10] See *McFarland Drinking Water l Investigation: US EPA Evaluation of Phase 1 and 2, January 2001*.

[11] Although this level translates to a 2 x 10^{-4} risk level, that level is within the EPA acceptable risk range of 10^{-4} to 10^{-6}.

[12] U.S. Geological Service , *A Retrospective Analysis on the Occurrence of Arsenic in Ground-Water Resources of the United States and Limitations in Drinking-Water-Supply Characterizations, 5/8/2000,* at http://co.water.usgs.gov/trace/arsenic.

[13] Compliance with the 10 ug/l MCL is based on a running annual average of four consecutive quarterly samples. Technically, a system would not be in violation of the new standard until three quarters of sample results above 10 ug/l were documented, unless any one sample result would put the system over the MCL even if the remaining sample results were zero. The first compliance monitoring period under the new rule is January 1, 2006 through December 31, 2007. The latest a system may begin compliance monitoring is October-December, 2007. At McFarland, if the first monitoring result is less than 10 ug/l, then the system would not be in violation until the rest of the samples were collected and evaluated.

Program is helping the states to acquire funding to install treatment systems where necessary. In conjunction with the states, the Water Program is also conducting training sessions and seminars on new treatment technologies.

II. SUMMARY OF OIG FINDINGS AND EPA RESPONSES TO OIG RECOMMENDATIONS

In the following section, Region 9 addresses each OIG draft report recommendation in detail. OIG draft report Chapter 1 does not contain any conclusions or recommendations.

A. Distinction Between NCP and Preamble to NCP

The OIG's conclusions are primarily based on the OIG's interpretation of the National Oil and Hazardous Substances Pollution Contingency Plan ("National Contingency Plan" or "NCP"), 40 C.F.R. Part 300, and the OIG's view of the Preamble to the NCP. The OIG views the Preamble as containing regulatory requirements equivalent in force to the regulatory requirements set forth in the NCP itself. In doing so, the OIG draft report misses a critical distinction between the NCP and the Preamble. The NCP is a regulation and establishes regulatory requirements; the Preamble is the agency's response to public comments on the draft NCP and does not establish any regulatory requirements.

As the NCP is a fully promulgated regulation, a proposed rule was published in the Federal Register, public comment was received, and a response to comments was prepared. This response to comments is set forth in the Preamble. As a response to comments, the Preamble can be helpful as guidance for interpreting the NCP, but is not itself a regulation.

OIG Comment

We realize that the Preamble does not establish regulatory requirements; however, the Preamble explains the rationale or intent of the NCP. It can provide evidence of what the Agency means or intends by the rule. The Preamble can be used to support the regulation. In addition, we added supporting information from the body of the NCP regulation to Chapter 3 of our report, regarding the use of 10^{-6} risk levels in setting remediation goals where there are multiple contaminants or multiple exposure pathways present.

B. National Issues

Region 9 notes that a number of the OIG's concerns stem from disagreement with the risk assessment approach set forth in EPA national guidance, which interprets the NCP. Among other issues, the OIG disagrees with EPA's approach to "lifetime" risk assessment. Region 9 suggests that these concerns may be more appropriately addressed at the national level.

OIG Comment

At least one other EPA Region (Region 3) has interpreted lifetime exposure similar to the OIG's interpretation. In a September 1993 amendment to the Record of Decision for the McAdoo Associates Superfund site in Pennsylvania, Region 3 indicated that lifetime exposure was equivalent to an exposure of 70 years. In addition, in commenting on an April 1984 risk assessment for the Enterprise Avenue Superfund site in Philadelphia, Pennsylvania, a Region 3 toxicologist noted that a risk level of 10^{-6} was more appropriate than 10^{-5} considering past EPA actions and current Agency thinking in estimating risks acceptable to the public.

C. Response to OIG Draft Report Recommendations from Chapter 2: Preliminary Remediation Goals Based on 30-year Lifetime Exposure Assumption

Region 9 based the PRGs it developed for McFarland on a lifetime residential exposure assumption of 30 years as indicated in the Agency's Risk Assessment Guidance for Superfund. The OIG draft report states that a 70-year exposure assumption, when there are multiple contaminants and exposure pathways, more accurately reflects the intent of the NCP to be more protective under such environmental conditions. Region 9 does not concur with this conclusion.

> **Distinction Between Lifetime Exposure and Residential Exposure Duration Assumption:** A 30-year exposure scenario is consistent with EPA national guidance, as explained in the Preamble to the NCP. The Preamble states that Superfund remedial projects will address lifetime[14] excess cancer risks using a reasonable maximum exposure scenario *in accordance with EPA guidance*. (55 Fed. Reg. 8710.) EPA national Superfund guidance calculates lifetime risk over 70 years based on a reasonable maximum exposure scenario, which is defined as a 30-year exposure in the case of residential PRGs and a 25-year exposure in the case of industrial PRGs. (RAGS, Vol. 1, Part A, at Exhs. 6-11 - 6-13, pp. 6-35 - 6-38.) Region 9 acted consistently with EPA guidance and the NCP in selecting a 30-year exposure scenario for the PRGs at McFarland. A 70-year exposure scenario is not consistent with EPA Superfund guidance or the Preamble, nor is it required by the NCP.

[14] The draft OIG report misinterprets the meaning of the term "lifetime risk" as used in the NCP to mean risks arising from a lifetime-long exposure. The interpretation used by Superfund is that "lifetime risk" refers to the risk accruing over a lifetime as the result of an exposure of unspecified duration. The relevant exposure duration for a Superfund site is defined in RAGS to be consistent with a "reasonable maximum exposure" (RAGS, Part A, Section 6.1.2; see also the discussion of "reasonable maximum exposure" in the NCP Preamble at 55 Fed. Reg. 8710). As defined by RAGS, a "reasonable maximum exposure" is one which represents "the highest exposure reasonably expected to occur at a site." RAGS defines a "reasonable maximum exposure" duration for a residential scenario as 30 years, as an upper-bound value for the number of years spent by individuals at one residence (RAGS, Part A, Section 6.4.1). RAGS Supplemental Guidance on standard default exposure factors defines the "reasonable maximum exposure" duration for a commercial/industrial exposure as "25 years at the same location" (OSWER Directive 9285.6-03, U.S. EPA 1991b).

EPA believes that the OIG draft report should draw a clearer distinction between "***lifetime exposure***" and the exposure ***duration*** assumption used for calculating a ***lifetime risk*** using a reasonable maximum exposure scenario.

Specifically, there are three places in the OIG draft report where the phrase "a lifetime residential exposure assumption of 30 years" appears ("At a Glance" and pp. 4 and 6). This phrase is inaccurate and misleading. The 30 year default residential exposure assumption is not meant as a lifetime exposure assumption; rather it is intended to represent a reasonable maximum value for duration of exposure occurring at any one residence. Thus, in these three places in the report, it would be more appropriate to say "a reasonable maximum residential exposure assumption of 30 years," leaving out the word "lifetime."

In this regard, please note that the Region agrees with the interpretations of ***lifetime exposure*** as presented in the 5 bullets on pp. 5-6. Specifically, those bullets reference certain technical references or protocols that equate lifetime exposure or the definition of "lifetime" with a 70-year daily exposure scenario. However, the Region does not agree that the intent of the NCP is for a risk assessment based on a ***lifetime exposure***. In fact, the phrase "lifetime exposure" does not appear any place in the NCP.

As we have noted in previous discussions and comments, the concept of ***lifetime risk*** does not automatically imply exposure over an entire 70 year lifetime. Region 9's assessments were based on this concept of "lifetime risk" in accordance with the NCP and Superfund guidance.

OIG Comment

After reviewing Region 9's comments on our draft report, we believe there is a fundamental difference of opinion between the OIG and the Region on interpreting the meaning and intent of the NCP.

Region 9 conducted the environmental assessment of McFarland using the NCP as one policy framework, along with EPA air and water quality standards. The NCP is a mandatory regulation, subject to formal rulemaking, printed in the Federal Register, and subject to public comment. The NCP essentially implemented the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (Pub. L. No. 96-510 and Pub. L. No. 99-499, or CERCLA/SARA). Where EPA guidance, which has not been the subject of formal rulemaking, differs from the intent of the NCP, we believe discrepancies should be resolved in favor of the NCP, until such time as it is revised using the same rulemaking process.

The Region discusses calculation of lifetime risk over a 70-year period based on a reasonable maximum residential exposure of 30 years. The NCP states that:

***…acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} to 10^{-6} using information on the relationship between dose and response.* (55 FR 8848, March 8, 1990).**

Based on information included in the reference text *Casarett and Doull's Toxicology - The Basic Science of Poisons* (Fifth Edition, 1996), we understand the term "excess upper bound lifetime cancer risk" to refer to exposures of 24 hours per day, 7 days per week, 365 days per year, for 70 years.

In addition, as noted in Chapter 2 of our report, EPA's Risk Assessment Guidance for Superfund defines lifetime, by convention, as 70 years. ATSDR defines lifetime exposure as being exposed to a substance every day for 70 years. EPA's Integrated Risk Information System uses excess lifetime cancer risk, calculated on a 24-hours-per-day, 7-days-per-week, 70-year-lifetime exposure.

D. Response to OIG Draft Report Recommendations from Chapter 3: Air and Soil Sampling Conducted Appropriately; Water Analyses Did Not Consider Interactions of Contaminants

The OIG draft report states on page 7 that "[T]he NCP requires that the cumulative risks of multiple contaminants in drinking water are no worse than 10^{-4} (1 per every 10,000 residents. However the NCP requires the use of 10^{-6} risk levels (1 per every 1,000,000 residents) in setting remediation goals where there are multiple contaminants or multiple exposure pathways, to provide an adequate margin of safety, because the interactions or synergistic effects among contaminants are unknown."

The OIG also states on page 9 of its report that: "[U]ntil the synergistic effects at multiple contaminants sites have been studied and quantified, we suggest that Region 9 explain why it is not using a 10^{-6} upper bound lifetime excess cancer risk in setting PRGs for McFarland for water that could be used as a drinking water source where multiple contaminants are present."

1. Synergistic Effects and Multiple Contaminants:

As noted, the OIG draft report states that the NCP requires a 10^{-6} level PRG whenever there are multiple contaminants (OIG draft report, p.7), or that synergistic effects must be considered in all cases where multiple contaminants are present.[15] Neither is true. The NCP states: "[T]he 10^{-6} risk level shall be used as the *point of departure* for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure." (40 C.F.R. §300.430(e)(2)(i)(A)). Similarly, the Preamble indicates that

14 It is EPA's goal to incorporate synergistic and antagonistic effects into risk assessments when there is sufficient credible scientific evidence of such effects and appropriate risk assessment tools are available. However, because synergistic and antagonistic effects are still an emerging scientific issue, there are very few data available on synergism or antagonism of specific mixtures that are useful in a risk assessment context.

synergistic effects may be one rationale for using 10^{-6} as a "point of departure," for selecting remediation goals, but only where the baseline risk assessment indicates that cumulative risks make ARARs non-protective. (55 Fed. Reg. 8713, 40 C.F.R. § 300.430(e)(2)(i)(A)(2))**.**

Thus, the 10^{-6} risk level would only be germane when "ARARs are not available or are not sufficiently protective (40 C.F.R. § 300.430(e)(2)(i)(A)(2))**.**
It is the Agency's decision to determine what is sufficiently protective for a given situation. Typically, to make a determination that ARARs were not protective, the Agency would need to determine that the cumulative risk was demonstrably non-protective. In other words, unless there is some indication that multiple contaminants, synergistic effects or additivity will make the ARARs non protective, the Agency presumption is that ARARs will be used.[16]

The Agency has not found any such indications in the McFarland investigation. The presence of multiple contaminants does not, in itself, demonstrate that ARARs are non-protective. Synergistic, antagonistic and additive effects are an emerging science for which few reliable data are available or demonstrative of non-protectiveness.[17] In the case of McFarland, consideration of synergistic and related effects would have been particularly difficult, because of the wide range of substances evaluated in the unusually broad geographic investigation. Instead, Region 9 sought to ensure protectiveness by approaching the McFarland investigation using conservative Superfund methodologies and protocols, even though the investigation included many more substances and a much larger geographical area than the typical Superfund investigation. The Region believes that the risk evaluation for this investigation was protective, given the comprehensive and conservative approach taken by the Region.

OIG Comment

As the Region noted above, "Synergistic, antagonistic, and additive effects are an emerging science for which few data are available…" We agree with the Region. We believe this lack of data is reason to be more, rather than less, protective when assessing the risk of multiple contaminants at a site. The NCP indicates that:

> ***EPA's preference, all things being equal, is to select remedies that are on the more protective end of the risk range.*** **(55 FR 8716, March 8, 1990).**

15 As noted in the Preamble, to consider 10^{-6} as the only protective level would be "incongruous with CERCLA's requirement to comply with ARARs . . . [many of which] are set at risk levels less stringent than 10^{-6}."

16 As noted in the Preamble, PRGs may be set at a risk level other than 10^{-6} based on uncertainty factors, including "the weight of scientific evidence concerning exposures and cumulative health effects and the reliability of exposure data." 55 Fed. Reg. at 8717.

In addition, the NCP states that:

> ***Where ARARs do not exist, or where the baseline risk assessment indicates that cumulative risks – due to additive or synergistic effects from multiple contaminants or multiple exposure pathways – make ARARs non-protective, EPA will modify preliminary remediation goals, as appropriate, to be protective of human health and the environment. For cumulative risks due to non-carcinogens, EPA will set the remediation goals at levels for individual chemicals such that the cumulative effects of exposure to multiple chemicals will not result in adverse health effects.*** **(55 FR 8713, March 8, 1990).**

There are no ARARs for some of the chemicals present at McFarland. In addition, there are multiple contaminants and multiple exposure pathways. The Region admits that there is insufficient data to assess additive or synergistic effects of the chemicals in the McFarland drinking water. Consequently, we believe that there is no reason consistent with protection of human health and the environment that justifies the decision to depart from the "point of departure" as the Region indicated in its comments.

In conclusion, we believe that our interpretation of NCP requirements is consistent with the letter and intent of the NCP, and is more protective of human health and the environment than the Region's interpretation.

2. <u>Distinction Between "10^{-4}"/"10^{-6}" and "1 per every 10,000"/ "1 per every 1,000,000</u>": The NCP does not require 1 x 10^{-4} cancer risk level as the upper boundary of EPA's risk range, as implied in the OIG report. The NCP is very explicit in requiring only a 10^{-4} risk level, which may equate to a risk of 2 x 10^{-4} or higher within the 10^{-4} risk range. As stated in the "Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions"(OSWER Directive 9355.0-30, page 4, April 22, 1991), "the upper boundary of the EPA risk range is not a discrete line at 1 x 10^{-4}. . . [a] specific risk estimate around 10^{-4} may be considered acceptable if justified based on site-specific conditions, including any remaining uncertainties on the nature and extent of contamination and associated risks."

Thus in discussing the risk-based requirements of the NCP, the Region suggests that it would be more appropriate for the OIG to use only the terms that actually appear in the regulation, namely "10^{-4}" and "10^{-6}," and not "1 per every 10,000 or 1,000,000," which may be misleading as to NCP requirements.

OIG Comment

We do not agree with Region 9's interpretation of the meaning or intent of 10^{-4} risk. The Office of Water, in its proposed arsenic MCL standard, used specific enumeration in discussing this risk, which reflects our view:

> ***The risk factors associated with various MCL options increase under this "What If?" analysis, with 10 ug/L being on the upper end or just outside of the Agency's 1 x 10^{-4} risk range and more stringent MCL options being more solidly under this risk ceiling.*** **(65 FR 38948, June 22, 2000)**

3. <u>OIG Risk Calculations for McFarland Drinking Water</u>: The last sentence in the section of the OIG's Report titled "Synergistic Effects of Multiple Contaminants in Drinking Water" (p. 8) states: "Taken on an additive basis, the cumulative risk for the 61 contaminants found in McFarland drinking water during the study exceeds the 10^{-4} risk allowed under the NCP." However, the report presents no supporting information on how this conclusion was reached; it is thus not possible for the Region to comment on its validity.

Region 9's approach to the assessment of McFarland's drinking water source was more rigorous and health protective than the typical drinking water assessment used for most sources. Consistent with Superfund guidance and as for any drinking water system in the nation, the Region used the current Safe Drinking Water Act standards (MCLs) to interpret the potential health significance of the concentrations of all regulated substances in McFarland's drinking water. In doing so, Region 9 notes that the mere presence of multiple substances, a situation which is typical of the vast majority of drinking water sources, does not imply that MCLs are not health protective.

OIG Comment

As noted above and in Chapter 3 of our report, Region 9 agreed that there has been limited research on the synergistic and additive effects of multiple contaminants in drinking water. Until there is sufficient research to allow an accurate determination of these effects, we believe that the intent of the NCP, as stated below, should be followed:

> ***EPA's preference, all things being equal, is to select remedies that are on the more protective end of the risk range.*** **(55 FR 8716, March 8, 1990).**

For the McFarland project, Region 9 then went beyond a typical drinking water assessment by including a large number of unregulated substances (i.e., substances without established drinking water standards); the protectiveness of these were assessed by comparison of their concentrations to health-based screening levels used nationally by Superfund or developed specifically for the McFarland project. In conclusion, the assessment of McFarland's drinking water source was more thorough than that used for sources in most other communities and the Region stands by its conclusion that McFarland's drinking water poses no unusual risks to public health.

OIG Comment

We agree with EPA's Office of Water that the additive risks of contaminants in McFarland drinking water, taking into account the risks of the arsenic present in the water, are on the upper end or just outside of the Agency's 1 x 10^{-4} risk range as noted in the proposed arsenic MCL rule:

> ***The risk factors associated with various MCL options increase under this "What If?" analysis, with 10 ug/L being on the upper end or just outside of the Agency's 1 x 10^{-4} risk range and more stringent MCL options being more solidly under this risk ceiling.*** **(65 FR 38948, June 22, 2000)**

III. EPA CONCLUSION ON THE OIG DRAFT REPORT

The OIG draft report reflects a fundamental disagreement with EPA national guidance on risk assessment that may be more appropriately addressed at a national level. In the McFarland investigation, as demonstrated above, Region 9 acted consistently with national guidance in all respects.

EPA disagrees with some of the conclusions in the OIG report and requests that the OIG incorporate EPA's suggested changes in the final report.

OIG Comment

There is a fundamental difference of opinion between the OIG and Region 9 in interpreting the meaning and intent of the NCP. We concur with the Region 3 toxicologist who stated that a risk level of 10^{-6} was more appropriate than 10^{-5} considering past EPA actions and Agency thinking in estimating risks acceptable to the public. We also concur with the Agency's Office of Water that the additive risks of contaminants, considering the risks of the levels of arsenic present in McFarland drinking water, are on the upper end or just outside of the Agency's 1 x 10^{-4} risk range. In conclusion, we believe that our interpretation of NCP requirements is consistent with the letter and intent of the NCP, and is more protective of human health and the environment than the Region's interpretation.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 17, 2006

OFFICE OF
RESEARCH AND DEVELOPMENT

MEMORANDUM

SUBJECT: ORD Response to OIG Revised Draft Public Liaison Report, "Review of Environmental Concerns at McFarland, California," Assignment No. 2004-01495, dated July 31, 2006

FROM: George Gray ***/s/ George Gray***
Assistant Administrator

TO: Wayne Nastri
Regional Administrator, Region 9

In general, we agree with the recommendations addressed directly to ORD. On August 10, 2006, the Office of Inspector General (OIG) verbally indicated they would incorporate ORD's requested changes to the recommendations. We appreciate the OIG's willingness to reword the recommendations as follows:

> **Recommendation 3-1** Identify currently available sources of information on the toxicology of contaminant mixtures that may be found in drinking water.
>
> **Recommendation 3-2** Continue support for research characterizing the joint toxic action (such as additivity, synergism, or antagonis) of contaminants in drinking water.

We do remain concerned with the third sentence on page 7, paragraph 2: "The synergistic effects are unknown because little research has been done by EPA, other agencies, private industry, and academia to investigate the synergistic or additive effects of multiple contaminants." The conduct of chemical mixtures toxicological research is complex and much work has been done over the years. However, much remains to be done and EPA's limited resources are strategically used to conduct targeted research on high priority contaminants of importance to EPA Program Offices and Regions. For mixtures research, this means EPA must design studies that test toxic endpoints, chemicals, dose levels and mixing ratios of environmental relevance; thus, not all adverse effects, chemicals and dose combinations can be tested. For drinking water, several mixtures of environmental concern are the subject of past or current research projects (e.g., disinfection by-products, pesticides, organotin compounds) whose goals are to characterize the joint toxic action of these compounds at environmentally relevant combinations.

Attached is ORD's Corrective Action Plan; corrective actions for both recommendations are ongoing. Therefore, we believe the final report should state this and be closed upon issuance.

We appreciate the opportunity to respond to this revised draft report. Should your staff have questions or require further information, please have them contact Cheryl Varkalis, ORD Audit Liaison, on 202-564-6688.

Attachment

cc: William Farland
Lek Kadeli
Jack Puzak
Alice Sabatini
Jorge Rangel
Cheryl Varkalis
Gregory Sayles
Jim Morant
Michael Loughran

ATTACHMENT II
ORD Response
to
OIG Revised Draft Public Liaison Report:
Review of Environmental Concerns at McFarland, California
Assignment No. 2004-01495

OIG Report Recommendation	ORD Response to OIG Recommendations	Action Official	Due Date
3-1 Identify currently available sources of information on the toxicology of contaminant mixtures that may be found in drinking water.	The EPA Science Inventory can search for relevant sources of information on the toxicology of contaminant mixtures in drinking water. The EPA Science Inventory is located at http://cfpub.epa.gov/si/ ORD will provide additional web sites for readily available sources of information.	AA/ORD	Ongoing

OIG Report Recommendation	ORD Response to OIG Recommendations	Action Official	Due Date
3-2 Continue support for research characterizing the joint toxic action (such as additivity, synergism, or antagonis of contaminants in drinking water.	In the "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures" (U.S. EPA, 2000), EPA updates guidance on conducting human health risk assessments of chemical mixtures and includes a discussion of research needs. In concert with these identified needs, ORD has established a substantial portion of the drinking water research program to study the toxicology of contaminant mixtures in drinking water. ORD recognized the need to enhance assessment tools for mixtures by establishing the Mixtures Risk Assessment Team. The Team's goals are to conduct technical chemical mixtures health risk assessments of high priority to the Agency's program offices, developing novel methods as required by the data, and generate guidance on chemical mixtures exposure assessments for use by program offices and regional risk assessors. ORD has dedicated considerable levels of resources to studying the toxicology of drinking water contaminant mixtures focusing on disinfection by-products (DBPs) including work in the following areas: ▪ Observing *in vivo* cancer and reproductive effects caused by a defined mixture of the nine regulated DBPs; ▪ Studying the liver toxicity associated with defined mixtures of the four regulated trihalomethane DBPs; ▪ Investigating the *in vitro* effects of mixtures of regulated haloacetic acid DBPs; and ▪ Studying the toxicity of treated drinking water- a complex, undefined mixture - with *in vivo* and *in vitro* tests. U.S. EPA, 2000a. *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures*. EPA/630/R-00/002, http://www.epa.gov/ncea/raf/pdfs/chem_mix/chem_mix_08_2001.pdf	AA/ORD	Ongoing

OIG Comment

We considered the Office of Research and Development's suggested revisions and modified Recommendation 3-2 accordingly. We revised Recommendation 3-1 based on the Office of Research and Development's suggested changes, but added a phrase for providing public access to the information.

We stand by our conclusion that limited research has been done by EPA, other agencies, and private industry to investigate the synergistic or additive effects of multiple contaminants, and that more research is needed in the area.

Appendix B

Distribution

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