Characterization of Exposure Potential during Activities Conducted on Synthetic Turf with Crumb Rubber Infill

OMB Control No. 0923-New

New Information Collection Request

Supporting Statement Part A –

Justification

Program Official: Angela Ragin-Wilson Title: Chief, Environmental Epidemiology Branch Phone: 770-488-3807 Email: ARagin@cdc.gov Fax: 770-488-1547

Date: April 27, 2017

Table of Contents

A.1. Circumstances Making the Collection of Information Necessary4
A.2. Purpose and Use of the Information Collection
A.3. Use of Improved Information Technology and Burden Reduction
A.4. Efforts to Identify Duplication and Use of Similar Information
A.5. Impact on Small Businesses or Other Small Entities
A.6. Consequences of Collecting the Information Less Frequently
A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency10
A.9. Explanation of Any Payment or Gift to Respondents11
A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions
A.12. Estimates of Annualized Burden Hours and Costs14
A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers16
A.14. Annualized Cost to the Federal Government16
A.15. Explanation for Program Changes or Adjustments17
A.16. Plans for Tabulation and Publication and Project Time Schedule
A.17. Reason(s) Display of OMB Expiration Date is Inappropriate18
A.18. Exceptions to Certification for Paperwork Reduction Act Submissions18
References19
List of Attachments

Part A. Justification

Goals of the research study: In July, 2016, an emergency Paperwork Reduction Act (PRA) clearance was granted for three activities under a research protocol titled "Collections Related to Synthetic Turf Fields with Crumb Rubber Infill" (OMB Control No. 0923-0054, expiration date 01/31/2017). Field work for Activity 1 was completed by December, 2016.

The goal for this research sub-study is to complete the pilot-level investigation to evaluate and characterize the human exposure potential to constituents in crumb rubber infill among a convenience sample of 60 field users (Activity 2) and to collect biological specimens (blood and urine) from 45 participants (Activity 3). While the sample design will not allow for generalization of results to the universe of field users with exposures to tire crumb rubber infill in synthetic turf fields in the United States, the research will provide valuable information to better understand the potential for human exposure to chemicals in tire crumb rubber. This investigative pilot sub-study is intended to set the stage for designing and implementing future human exposure studies, if feasible.

Intended use of the resulting data: To inform future public health decisions by estimating the exposure potential for persons with contact to crumb rubber. The research activities are anticipated to substantially add to knowledge on the topic, fill key data gaps, and improve exposure characterization capabilities needed to inform further evaluation.

Methods to be used to collect: Collections include: 1) enrolling and administering questionnaires to 60 field users, children and youth (7-17 years) and adults, from a sub-set of the 40 previously enrolled facilities with fields; 2) conducting a full exposure measurement sub-study among a subset of 45 of the 60 field users, including, environmental sampling, personal air monitoring, and dermal wipe sampling; and 3) recording videography sessions for 24 of the 45 field users enrolled in the exposure measurement sub-study. Additionally, biological specimens will be collected from participants in the exposure measurement sub-study. Blood and urine will be collected pre-activity and post-activity and held in a biorepository.

Respondents: A convenience sample of field users (e.g., athletes) who are persons with potential for high exposures to contaminants in synthetic turf. The sub-study aims to include substantially more field users than any previous study in the United States.

How data will be analyzed: To the extent possible, data will be analyzed using non-parametric and parametric statistical methods. If possible, the data will be used for exposure modeling and to perform screening level exposure evaluations.

A.1. Circumstances Making the Collection of Information Necessary

In recent years, the public has raised concerns about the use and safety of synthetic turf with crumb rubber infill. In November, 2015, the White House Council on Environmental Quality (CEQ), requested that the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry (CDC/ATSDR) and the United States Environmental Protection Agency (US EPA), in collaboration with the Consumer Product Safety Commission (CPSC), develop a *Federal Research Action Plan* to address the issues surrounding synthetic turf with crumb rubber infill. On February 12, 2016, US EPA, ATSDR, and the CPSC, released the *Federal Research Action Plan* on *Recycled Tire Crumb Used on Playing Fields and Playgrounds*.¹

As part of the work under the *Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds*, the Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (US EPA) were granted a six-month emergency OMB approval for a research protocol titled "Collections Related to Synthetic Turf Fields with Crumb Rubber Infill" (OMB Control No. 0923-0054, expiration date 01/31/2017) on July 22, 2016. The research goals for three activities in the protocol are pilot-level investigations to evaluate and characterize: the chemical composition and use of crumb rubber infill in synthetic turf using a convenience sample of nine tire recycling manufacturing plants and 40 facilities that use synthetic turf fields (Activity 1); the human exposure potential to constituents in crumb rubber infill among a convenience sample of 60 field users (Activity 2); and collection of biological specimens (blood and urine) from 45 participants from Activity 2 (Activity 3).

Since the six-month emergency PRA clearance was granted, ATSDR and US EPA have completed Activity 1 by consenting and sampling 40 synthetic turf fields with crumb rubber infill across the United States by December, 2016. These activities are reported in the "Status Report on the Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds." The Status Report was released on December 30, 2016.²

This new information collection request (ICR) proposes to use fields previously identified during Activity 1 to investigate the potential for human exposure to environmental constituents from

¹ Accessed 6/21/2016 at <u>https://www.epa.gov/chemical-research/federal-research-recycled-tire-crumbs-used-playing-fields</u> and at <u>https://www.epa.gov/chemical-research/federal-research-action-plan-recycled-tire-crumb-used-playing-fields</u>.

² Accessed 1/24/2017 at <u>https://www.epa.gov/chemical-research/december-2016-status-report-federal-research-action-plan-recycled-tire-crumb</u>.

contact with crumb rubber infill. Due to the limited time constraints and field activity schedules, ATSDR and US EPA are submitting a new one-year ICR to complete Activities 2 and 3 for the human exposure characterization component of the research activities.

ATSDR, in cooperation with the US EPA, is authorized by the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) and the Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9604(i)(1)(E), (7), (9), (15) and 9626(a)] to collect this study data (Attachment 1).

The agencies published the 60-day Federal Register Notice on 02/10/2017 (Attachment 2).

Background

Synthetic turf fields are used across the United States with more than 12,000 fields currently in use (Synthetic Turf Council, 2015). These fields are often made with rubber granules from recycled tire waste used as infill (referred to as crumb rubber). There are differences in the types of crumb rubber, including differences due to processing and coating (Gomes et al, 2010). To date, there has been no comprehensive evaluation of crumb rubber material as previous studies are limited, often due to small sample size.

To date approximately 30 peer-reviewed studies and a number of other reports have been published on synthetic/artificial turf and crumb rubber infill. These studies span four main topic areas: product sampling and chemical composition studies, biomonitoring studies, bioavailability studies, and toxicological/*in vitro* studies. However, the majority of the studies are limited in scope and in sample size. While the majority of studies identified numerous chemical compounds within the crumb rubber, including volatile organic compounds (VOCs), semi-volatile organic compounds (SVOCs), and metals, the measured concentrations were generally low (Bocca et al, 2009; Ginsberg et al, 2011; Simcox et al, 2011; Kim et al, 2012; Marsili et al, 2014). One exception is zinc, which was found at high levels in most of the samples tested (Bocca et al, 2009; Kim et al, 2012; Marsili et al, 2014). However, chemical composition variability may be high even among rubber granules from the same origin (Menichini et al, 2011).

Limited data are available on the bioavailability of crumb rubber infill and the biomonitoring of persons exposed to crumb rubber infill. These studies are limited by laboratory methodology for stimulated gastric fluids and by small sample size and large inter-individual variation. The studies indicated that the rubber granules had low bioaccessibility for polycyclic aromatic hydrocarbons (PAHs), but lead was highly bioaccessible in the gastric fluid (Zhang et al, 2008; Kim et al 2012). However, previous work has shown that tire crumb samples with the highest total extractable lead content had the lowest bioaccessibility values for lead (EPA, 2009). The biomonitoring study measured only one PAH, 1-hydroxypyrene, in seven football (soccer)

players. While the study showed that uptake of PAHs by the participants was minimal, the sample size was very small and likely did not represent the target population. There have been anecdotal reports of cancer clusters in athletes and other deleterious effects from contact with crumb rubber infill (ESPN E:60). To date, the studies have not shown elevated health risks from use of and contact with synthetic turf. However, the studies are limited and do not comprehensively address the concerns about the potential health risks associated with exposure to chemicals in the crumb rubber infill.

A.2. Purpose and Use of the Information Collection

The research study protocol (Attachment 6) includes the specific objectives to characterize human exposures to the tire crumb rubber in a convenience sample of field users (Activity 2); and to collect biological specimens from users of tire crumb rubber synthetic turf fields (Activity 3) to guide future research activities.

The activities will be conducted on a one-time basis. The data will be analyzed by scientists at ATSDR and US EPA to answer key questions related to crumb rubber infill in synthetic turf. There are specific limitations within each activity. The limitations include low sample size and a sample that may not be nationally representative due to the convenience sampling methods employed. However, we feel that the activities set forth will help characterize some exposure patterns for individuals with high exposure potential.

While the sample design will not allow for generalization of results to the universe of field users with exposures to tire crumb rubber in synthetic turf fields in the United States, the research will provide valuable information to better understand and identify the important potential chemical and microbiological exposures. This investigative pilot sub-study is intended to set the stage for designing and implementing future human exposure studies, if feasible. It is important to communicate to the public and other stakeholders that the study activities are not designed to and will not be sufficient by themselves to directly answer the public's question about safety but will contribute to the more extensive research portfolio necessary to achieve that goal in the longer term.

A.2.1. Characterization of Exposure Potential during Activities Conducted on Synthetic Turf with Crumb Rubber Infill

The Activity 2 sub-study will be conducted to include an assessment of potential exposures to potentially harmful constituents. Any materials disseminated to the public and other stakeholders will clearly communicate that the study activities are not designed to and will not be sufficient by themselves to directly answer the public's question about safety, but will

contribute to the more extensive research portfolio necessary to achieve that goal in the longer term.

The sub-study will focus on exposure patterns in a small number of persons who are thought to have the potential for high exposure to chemical contaminants in crumb rubber infill, specifically adults and youth that routinely use synthetic turf fields with crumb rubber infill. We aim to conduct the exposure characterization study among field users at a sub-set of fields included in Activity 1. We previously obtained consent from nine fields for the recruitment of individuals who play on their fields. Respondents will be categorized into specific age/activity groups, such as professional athletes, college athletes, high school athletes, youth ages 10-12, and children ages 7-9. Interested field users will be provided study fact sheets, screened for eligibility, and consented (Attachment 4a, 4b, and 4c). We will administer a detailed questionnaire to determine adult and adolescent activities associated with the use of synthetic turf with crumb rubber infill and related exposure factors (Attachment 4d). For children ages 7-9 and youth ages 10-12, we will ask the parent/guardian to answer the survey questions (Attachment 4e).

We will conduct a more detailed exposure measurement sub-study on a sub-sample of 45 of the 60 enrolled respondents. The sub-study will include personal air monitoring and dermal wipe sampling (Attachment 4f).

A further subset of 24 of the 45 sub-study respondents will be asked to participate in a videography session during live activity to further characterize different exposure scenarios. Additionally, researchers will use extant video of people engaged in the activities of interest. The information obtained in these activities will be used to characterize exposure patterns and activities related to exposure to chemicals in crumb rubber infill.

Additionally, we aim to develop a repository of biological specimens which will be used for future developmental research and hypothesis generation of exposure to chemicals in tire crumb rubber. While the biological specimen activity was not included in the Federal Research Action Plan, the agencies decided to include the collection of biological specimens in the current research activities. At this time, we do not know what the most relevant analyses might be for the synthetic turf field exposure scenarios. The challenge inherent in this research will be the ability to demonstrate that the exposure is to tire crumb rubber constituents and not simply reflecting exposures to chemicals from other sources in people's lives.

CDC will ask the 45 individuals recruited for the sub-study to provide blood and urine samples both pre-activity and post-activity. Prior to blood draw, the phlebotomist will ask the respondent a few questions to determine their eligibility for blood collection (Attachment 4g). The biological specimens will likely not be analyzed in the current project time frame but will be archived indefinitely for future analysis.

A.3. Use of Improved Information Technology and Burden Reduction

ATSDR and US EPA plan to use electronic reporting in the form of computer-assisted interviews (CAIs) for data collection; the questionnaire was developed using Epi Info. We anticipate the eligibility screening will also occur electronically prior to the questionnaires for the field users. The questionnaires will be administered by trained study interviewers. The questionnaires will incorporate computer-generated skip patterns thus alleviating respondent burden for inapplicable questions.

Additionally, some field users will be videotaped during real or simulated activity. This technology will improve data quality by allowing the investigators to accurately transmit video recording to objective measures of respondent activities, rather than relying solely on self-reporting via questionnaires, which may be prone to bias. The videography sessions will incur no additional burden, because they will take place at the same time as the full exposure measurement sub-study. In addition, the use of extant video of people engaged in activities of interest will be analyzed; thereby, imposing no additional burden on the public.

A.4. Efforts to Identify Duplication and Use of Similar Information

The ICR describes a joint effort between the US EPA and ATSDR, in coordination with the CPSC, to conduct a study. CPSC has indicated its own plans to conduct a limited study of playground material with recycled tire material. However, as our studies do not incorporate playground material, there will be no duplication of efforts. Playground material, consisting of rubber mats and/or rubber mulch, could potentially have different constituents and/or exposure potential. Specifically, the rubber mats may have different chemical constituents due to the use of bonding agents and materials. For the rubber mulch used in playgrounds, the rubber pieces are likely larger than the crumb rubber infill which could result in differing exposures. Playground use and activity information, if collected by CPSC, may be useful for exposure modeling as a follow-on activity to exposure modeling for synthetic turf field users.

Several studies have performed measurements at synthetic turf fields for selected metal or organic chemical analytes (Schiliro et al., 2013; Menchini et al., 2011; Shalat, 2011; Cal-OEHHA, 2010; Simcox et al., 2011; Van Rooij and Jongeneelen, 2010; Highsmith et al., 2009; NYDEC, 2009; Vetrano and Ritter, 2009; Castellano et al., 2008; Dye et al., 2006). Most of these measurements have been for particles, metals, or organics in air while only a few studies

measured chemicals present on field surfaces using wipe samples (NYDEC, 2009; Highsmith et al., 2009; CPSC, 2008; Cal-OEHHA, 2007). Concentrations of chemicals in the air of indoor fields have generally been found to be higher than those at outdoor fields. Very few studies have reported biomonitoring data (Van Rooij and Jongeneelen, 2010; Castellano et al., 2008). In both cases, 1-hydroxypyrene was measured as a marker of exposure to pyrene, and no elevated levels were found following synthetic field sports use. Several studies collected personal air samples from people engaged in activities on synthetic turf fields (Menichini et al., 2011; Shalat, 2011; Simcox et al., 2011; Vetrano and Ritter, 2009; Moretto et al., 2007). No dermal sample collection reports have been identified. Only a few studies have examined microbiological populations at synthetic turf fields (Bass and Hintze, 2013; Keller, 2013; Cal-OEHHA, 2010; Vidair, 2010: McNitt et al., 2006).

There are other studies currently being conducted, primarily by the California Office of Environmental Health and Hazard Assessment (OEHHA). While there could be slight duplication of efforts with the California OEHHA activities, their activities are limited to the state of California. The data collection described in this ICR will target field users across the US and will not focus on one state alone.

Consultation between the federal research team and Cal-OEHHA researchers will be used to identify and implement methods and approaches that will, where feasible, produce comparable data. There as a recent study by the Washington State Department of Health; however, there is no duplication of efforts as the study focused on cancer incidence among soccer players residing in the state at the time of diagnosis.

Other attempts at identifying activities that could results in duplication of efforts, including literature searches, attendance at national meetings, and consultations with other federal and state agencies, did not reveal any other ongoing activities related to crumb rubber infill in synthetic turf.

A.5. Impact on Small Businesses or Other Small Entities

The activities will involve field users which will likely not involve small businesses or other small entities.

A.6. Consequences of Collecting the Information Less Frequently

The activity will be a one-time collection in accordance with the Federal Research Action Plan on Recycled Tire Crumbs Used on Playing Fields and Playgrounds, and the respondents will respond once per form.

However, the biological specimen collection will occur two times in a 24-hour period, but no additional information will be collected (e.g. no additional exposure measurement questionnaire). If the specimen collections are not obtained, the lack of knowledge regarding chemical constituents of crumb rubber infill and exposure potential to chemicals in crumb rubber infill will persist. Responsive and actionable public health recommendations cannot be implemented.

There are no technical or legal obstacles to reducing burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The following special circumstance applies to this information collection. The respondents for research activity will be drawn from a convenience sample; therefore, the results are not intended to be generalized to the universe of field users.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

- A. A 60-day Federal Register Notice was published in the *Federal Register* on 02/10/2017.
- B. During the 60-day public comment period, three comments from the public were received. The agencies' response is provided in Attachment 2a.
- C. ATSDR and US EPA have consulted directly with the White House CEQ and CPSC to obtain their views on the public health issue/concern surrounding crumb rubber infill in synthetic turf. These federal partners have drafted the *Federal Research Action Plan for the Use of Recycled Tires in Synthetic Turf*. One of the activities outlined in the action plan is described in this ICR.

The agencies submitted their draft research protocol for external peer review on May 2, 2016. The agencies' response is provided in Attachment 3.

Table A.8.1. 2016 ATSDR External Consultations

Name	Title	Affiliation	Phone	Email
FEDERAL CONSULTANTS				
Annette Guiseppi-Elie, PhD	Associate Director for Exposure Science	US EPA	(919) 541-4651	<u>TireCrumbs@epa.gov</u>
Eric Hooker, MS, DABT	Toxicologist	CPSC	(301) 987-2516	<u>EHooker@cpsc.gov</u>
Kent Thomas, BSPH	Research Physical Scientist	US EPA	(919) 541-4651	<u>TireCrumbs@epa.gov</u>

Table A.8.2. 2016 Consultations with CDC NCEH Laboratories

Name	Title	Affiliation	Phone	Email
David Chambers, PhD	Lab Chief	Tobacco and Volatiles Branch	(770) 488-0185	<u>mzz7@cdc.gov</u>

A.9. Explanation of Any Payment or Gift to Respondents

A.9.1. Characterization of Exposure Potential during Activities Conducted on Synthetic Turf with Crumb Rubber Infill

Incremental tokens of appreciation in the form of gift cards will be provided to maximize the agencies' ability to recruit respondents.

- Eligible respondents who provide informed consent and who complete the activity questionnaire will receive a gift card (\$25) as a token of thanks upon completion of the activities.
- Respondents who undergo the exposure measurements component, will receive additional gift cards for the monitoring and biological specimen collection. The maximum received for this portion of the activity is \$40, specifically:
 - 0 Pre-activity urine and blood collection: \$15
 - 0 Post-activity, including activity monitoring and blood and urine collection: \$25
- Respondents who also participate in the video portion will receive an additional gift card (\$10) as a token of thanks upon completion of the video activity.

The gift cards will be offered at a total monetary level that is commensurate with previously approved collections (i.e., maximum of \$75 for completion of all increments if selected for all parts of the research, with potential maximum of four increments).

Table A.9.2: Activities 2 and 3: Estimated Number of Respondents and Tokens ofAppreciation by Level of Collections Completed

Collections	No. Respondents out of 60 Initially Enrolled	Total Tokens per Respondent
Questionnaire only	15	\$25
Questionnaire plus 2 Specimen Collections	21	\$65
Questionnaire, 2 Specimen Collections, plus	24	\$75
Videography	·	÷. •

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NCEH/ATSDR Information Systems Security Officer (ISSO) has approved a Data Privacy & Security Plan to ensure measures are in place to protect participant data while using Epi Info[™] software. The system's Security Plan defines the process for handling security incidents. The system's team and the Office of the Chief Information Security Officer (OCISO) share the responsibilities for event monitoring and incident response. The team will direct reports of suspicious security or adverse privacy-related events to the NCEH/ATSDR ISSO, CDC Helpdesk, or to the CDC Incident Response team. The CDC OCISO reports to the HHS Secure One Communications Center, which reports incidents to US-CERT as appropriate. The Privacy Impact Assessment (PIA) is found in Attachment 5.

The records will follow the required disposition schedules under: 1) CDC/ATSDR Records Control Schedule; and 2) EPA Records Schedule 566.

A.10.1. Characterization of Exposure Potential during Activities Conducted on Synthetic Turf with Crumb Rubber Infill

For the study, IIF will be collected from individual respondents. Therefore, the Privacy Act will apply. All privacy protections will be in place by which applicable Privacy Act requirements will be adhered to the extent allowable by law.

The applicable Privacy Act System of Records Notices (SORNs) will be ATSDR No. 09-19-0001 "Record of Persons Exposed or Potentially Exposed to Toxic or Hazardous Substances" (retrievable by name or SSN), CDC No. 09-20-0136 "Epidemiologic Studies and Surveillance of Disease Problems" (retrievable by name and ID number), and US EPA No. EPA-34 "Medical and Research Study Records of Human Volunteers" (retrievable by name and ID number).³ The SORNs describe the privacy protections that must be in place to secure the information.

The following IIF categories apply to this information collection: name, biological specimens. The consent forms require a name and signature (Attachment 4c). US EPA and CDC/ATSDR will maintain personal information within the consent forms in a locked file cabinet. All IIF information in the electronic survey instruments (eligibility screening form) will be collected using the CDC-approved Epi Info[™] software, maintained in a password-protected network in project-specific password-protected folders, and transferred via encrypted FTP site. If it is necessary for data collected in the field to be stored electronically, the computers will be password protected and hard drives encrypted.

Biological specimens collected as part of the study will be labeled with an assigned study ID number.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The study protocol (Attachment 6) has been submitted and approved by the CDC IRB (Attachment 7). Additionally, the protocol and IRB documentation has been submitted and approved by the US EPA Human Subjects Research Review Official (Attachment 9). All human subjects protections will be implemented.

ATSDR and US EPA intend to collect the minimum amount of sensitive information necessary to meet the objectives of the three research activities. Some of the information could be viewed as sensitive by the respondents, specifically related to field procedures or videotaping. All respondents will be consented and informed that their participation is voluntary, that they will not be named in any publications, and that they can choose to not answer any question.

³ SORNS accessed 01/21/2016

¹⁾ ATSDR No. 09-19-0001 - Federal Register: January 25, 2011 (Volume 76, Number 16, Page 4432-4435)

²⁾ CDC No. 09-20-0136 - Federal Register: January 25, 2011 (Volume 76, Number 16, Page 4458-4460)

³⁾ EPA 34 - Federal Register: February 22, 2002 (Volume 67, Number 36, Page 8259-8260)

A.12. Estimates of Annualized Burden Hours and Costs

The total estimated time burden for the study titled "Characterization of Exposure Potential during Activities Conducted on Synthetic Turf with Crumb Rubber Infill" is 174 hours. Estimated annualized burden hours are presented below.

A.12.1. Characterization of Exposure Potential during Activities Conducted on Synthetic Turf with Crumb Rubber Infill

For the 75 initial respondents, the eligibility screening is estimated to take 5 minutes resulting in a burden of 6 hours. For the activity questionnaire, we estimate the respondent burden to be 30 hours, based on 60 respondents at 30 minutes. Breaking down by respondent groups, we estimate that 60 percent of the sixty will be adults and adolescents who respond for themselves and 40 percent of the sixty will be parents/guardians responding on behalf of their of children ages 7 to 12.

A sub-sample of 45 of the 60 initial respondents will participate in a full exposure characterization, including personal monitoring and biological specimen collection. We estimate this will take 3 hours per respondent, resulting in a burden of 135 hours. Adult and adolescent respondents in the exposure measurements sub-study will be consented to donate blood and urine specimens. Parent or guardian respondents will provide permission for their assenting youth or child to provide specimens. Prior to blood collection, the phlebotomist will ask a set of safety exclusion questions. We estimate this will take 2 minutes per respondent, resulting in a burden of 2 hours.

A further sub-sample of 24 of the 45 respondents in the exposure measurements sub-study will participate in a video session of either simulated or active sporting; however, the video will be recorded by trained study staff or contractors concurrently with the exposure measurements collection and will not result in additional respondent time burden.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Adult/	Eligibility	41	1	5/60	4
Adolescent	Screening				

Table A.12.1.a: Estimated Annualized Burden Hours

	Script				
Field Users	Adult and Adolescent Questionnair e	36	1	30/60	18
	Exposure Measuremen t Form	27	1	3	81
	Phlebotomist Safety Exclusion Questions Form	27	1	2/60	1
Parents/ Guardians of Youth/Child Field Users	Eligibility Screening Script	34	1	5/60	3
	Youth and Child Questionnair e	24	1	30/60	12
	Phlebotomist Safety Exclusion Questions Form	18	1	2/60	1
Youth/Child Field Users	Exposure Measuremen t Form	18	1	3	54
Total					174

The adult and adolescent field users are assumed to be college student athletes with an earning potential, if employed, of \$7.25/hour based on the federal minimum wage. See http://www.dol.gov/general/topic/wages/minimumwage. The hourly wage for parent/guardian respondents of youth or child field users is assumed to be \$23.23 for all occupations based on the Bureau of Labor Statistics *May 2015 National Occupational Employment and Wage Estimates*. See http://www.bls.gov/oes/current/oes_nat.htm. We assume that the parents/guardians will attend the 3-hour exposure measurement session for their youth or child, who is not a wage earner; therefore, by proxy, we attribute \$23.23 per hour for respondent cost burden for this activity.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adult/ Adolescent Field Users	Eligibility Screening Script	4	\$7.25	\$29.00
	Adult and Adolescent Questionnaire	18	\$7.25	\$130.50
	Exposure Measurement Form	81	\$7.25	\$587.25
	Phlebotomist Safety Exclusion Questions Form	1	\$7.25	\$7.25
Parents/ Guardians of Youth/Child Field Users	Eligibility Screening Script	3	\$23.23	\$69.69
	Youth and Child Questionnaire	12	\$23.23	\$278.76
	Phlebotomist Safety Exclusion Questions Form	1	\$23.23	\$23.23
Youth/Child Field Users	Exposure Measurement Form	54	\$23.23	\$1,254.42
Total				\$2,353.10

Table A.12.1.b: Estimated Annualized Burden Costs

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There will be no additional capital and maintenance costs for study described in this ICR for respondents or record keepers.

A.14. Annualized Cost to the Federal Government

In total, the estimated annual cost to the government is \$2.12 million, based on the estimated costs in the *Federal Research Action Plan*.

- The estimated average annualized cost of the program is \$1,119,660.
 - 0 Personnel: \$1,059,660 per year.
 - The annual personnel costs are based on a FTE at GS-13/1 with an estimated 12 full time staff.
 - 0 Travel: \$60,000. This amount is based on the number of site visits conducted.
- Other project requirements, including but not limited to, laboratory analysis, bioavailability studies, and hazard assessments, are estimated to cost \$1.0 million.

A.15. Explanation for Program Changes or Adjustments

This is a new information collection request.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Information collections will begin at the time of PRA clearance and are expected to take up to one year. Upon completion of data collection and laboratory analysis, ATSDR and US EPA may report on the various activities to the respondents and to the public. The research will be described in a final report. The report will help answer some of the key questions that have been raised about tire crumb used in artificial turf fields, and will provide a better understanding of potential exposures that athletes and others may experience by using these fields.

As stated earlier in this Supporting Statement, as the sample design for this study will not allow for generalization of results to the universe of synthetic turf fields in the United States, this investigative pilot study is only intended to set the stage for designing and implementing future human exposure studies. For all publications, presentations, and materials disseminated to the public and other stakeholders of this study's findings, it will be clearly communicated that the study activities are not designed to and will not be sufficient by themselves to directly answer the public's questions about safety but will implement the preliminary research necessary to achieve that goal in the longer term.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

- 1. "About Synthetic Turf." <u>http://www.syntheticturfcouncil.org.</u> Synthetic Turf Council [accessed November 5, 2015].
- 2. Gomes J, Mota H, Bordado J, et al. Toxicological assessment of coated versus uncoated rubber granulates obtained from used tires for use in sports facilities. 2010. *J Air Waste Manage Assoc.* 60: 741-6.
- 3. Bocca B, Forte G, Petricci F, Constantini S, Izzo P. Metals contained and leached from rubber granulates used in synthetic turf areas. 2009. *Sci Total Environ*. 407: 2183-90.
- 4. Ginsberg G, Toal B, Kurland T. Human health risk assessment of synthetic turf fields based upon investigation of five fields in Connecticut. 2011. *J Toxicol Environ Health A*. 74: 1150-74.
- Simcox NJ, Bracker A, Ginsberg G, Toal B, Golembiewski B, Kurland T, Hedman C. Synthetic turf field investigation in Connecticut. 2011. *J Toxicol Environ Health A*. 74: 1133-49.
- 6. Kim S, Yang JY, Kim HH, Yeo IY, Shin DC, Lim YW. Health risk assessment of lead ingestion exposure by particle sizes in crumb rubber on artificial turf considering bioavailability. 2012. *Environ Health Toxicol*. 27: e2012005.
- 7. Marsili L, Coppola D, Bianchi N, Maltese S, Bianchi M, Fossi MC. Release of polycyclic aromatic hydrocarbons and heavy metals from rubber crumb in synthetic turf fields: preliminary hazard assessment for athletes. 2014. *J Environ Anal Toxicol.* 5: 1-8.
- Menichini E, Abate C, Attias L, De Luca S, di Domenico A, Fochi I, Forte G, Iacovella N, Iamiceli AL, Izzo P, Bocca B. Articifical-turf playing fields: contents of metals, PAHs, PCBs, PCDDs, and PCDFs, inhalation exposure to PAHs and related preliminary risk assessment. 2011. *Sci Total Environ*. 409: 4950-7.
- 9. Zhang J, Han I, Zhang L, Crain W. Hazardous chemicals in synthetic turf materials and their bioaccessibility in digestive fluids. 2008. *J Expo Sci Environ Epidemiol*. 18: 600-7.
- U.S. Environmental Protection Agency. A Scoping-Level Field Monitoring Study of Synthetic Turf Fields and Playgrounds. National Exposure Research Laboratory, Office of Research and Development. 2009. 1-105.
- 11. ESPN E:60 The Turf War. <u>http://espn.go.com/espnw/video/14045313/e60-excerpt-turf-war</u>. ESPN [accessed January 12, 2016].

- 12. Celeiro, M. et al. Investigation of PAH and other hazardous contaminant occurrence in recycled tyre rubber surfaces: case study: restaurant playground in an indoor shopping centre. 2014. *Int J Environ Anal Chem.* 94(12): 1264-1271.
- Llompart, M; Sanchez-Pardo, L; Lamas, J; Garcia-Jares, C; Roca, E. Hazardous organic chemicals in rubber recycled tire playgrounds and pavers. 2013. *Chemosphere*. 90(2):423-31.
- Highsmith, R; Thomas, KW; Williams, RW. A Scoping-Level Field Monitoring Study of Synthetic Turf and Playgrounds; EPA/600/R-09/135. National Exposure Research Laboratory, U.S. Environmental Protection Agency. 2009. <u>http://cfpub.epa.gov/si/si_public_record_report.cfm?</u> dirEntryId=215113&simpleSearch=1&searchAll=EPA%2F600%2FR-09%2F135.
- Mota, H., et al. Coated rubber granulates obtained from used tyres for use in sport facilities: A toxicological assessment. 2009. *Ciência & Tecnologia dos Materiais*. 21(3-4): 26-30.
- 16. Krüger, O; Kalbe, U; Richter, E; Egeler, P; Rombke, J; Berger, W. New approach to the ecotoxicological risk assessment of artificial outdoor sporting grounds. 2013. *Environ Pollut*. 175:69-74.
- 17. Rhodes, EP; Ren, Z; Mays, DC. Zinc Leaching From Tire Crumb Rubber. 2012. Environ Sci Technol. 46(23):12856-63.
- Li, X; Berger, W; Musante, C; Incorvia Mattina, MJ. Characterization of Substances Released from Crumb Rubber Material Used on Artificial Turf Fields. 2010. *Chemosphere*. 80(3):279-85.
- 19. New York Department of Environmental Conservation (NYDEC). An assessment of chemical leaching, releases to air and temperature at crumb-rubber infilled synthetic turf fields. 2009. <u>http://www.dec.ny.gov/docs/materials_minerals_pdf/crumbrubfr.pdf</u>.
- Nilsson, NH; Malmgren-Hansen, B; Thomsen, US. Mapping Emissions and Environmental and Health Assessment of Chemical Substances in Artificial Turf. Danish Ministry of the Environment, Environmental Protection Agency. 2008. <u>http://www2.mst.dk/udgiv/publications/2008/978-87-7052-866-5/pdf/978-87-7052-867-2.pdf</u>.
- 21. Incorvia Mattina, MJ; Isleyen, M; Berger, W; Ozdemir, S. Examination of Crumb Rubber Produced from Recycled Tires. Department of Analytical Chemistry. The Connecticut Agricultural Research Station, New Haven, CT. 2007. <u>http://www.ct.gov/caes/lib/caes/documents/publications/fact_sheets/</u> <u>examinationofcrumbrubberac005.pdf</u>.

- Pavilonis, BT, Weisel, C P, Buckley, B and Lioy, PJ. Bioaccessibility and Risk of Exposure to Metals and SVOCs in Artificial Turf Field Fill Materials and Fibers. 2014. *Risk Analysis*. 34: 44–55.
- 23. Lioy, P; Weisel, C. Crumb Infill and Turf Characterization for Trace Elements and Organic Materials. Report prepared for NJDEP, Bureau of Recycling and Planning. 2011.
- 24. California Office of Environmental Health Hazard Assessment. Evaluation of Health Effects of Recycled Waste Tires in Playground and Track Products. Prepared for the California Integrated Waste Management Board. 2007. <u>http://www.calrecycle.ca.gov/publications/Detail.aspx?PublicationID=1206</u>.
- 25. Schilirò, T; Traversi, D; Degan, R; Pignata, C; Alessandria, L; Scozia, D; Bono R; Gilli, G. Artificial Turf Football Fields: Environmental and Mutagenicity Assessment. 2013. Arch Environ Contam Toxicol. 64(1):1-11.
- 26. Shalat, SL. An Evaluation of Potential Exposures to Lead and Other Metals as the Result of Aerosolized Particulate Matter from Artificial Turf Playing Fields. Submitted to the New Jersey Department of Environmental Protection. 2011. <u>http://www.nj.gov/dep/dsr/publications/artificial-turf-report.pdf</u>.
- 27. Van Rooij, JGM; Jongeneelen, FJ. Hydroxypyrene in Urine of Football Players After Playing on Artificial Sports Fields with Tire Crumb Infill. 2010. *Int Arch Occup Environ Health*. 83(1):105-10.
- Vetrano, KM; Ritter, G. Air Quality Survey of Synthetic Turf Fields Containing Crumb Rubber Infill. Prepared by TRC for the New York City Department of Mental Health and Hygiene, New York, NY. 2009. http://www.nyc.gov/html/doh/downloads/pdf/eode/turf_aqs_report0409.pdf
- Castellano, P; Proietto, AR; Gordiani, A; Ferrante, R; Tranfo, G; Paci, E; Pigini, D. Assessment of exposure to chemical agents in infill material for artificial turf soccer pitches: development and implementation of a survey protocol. 2008. *Prev Today*. 4(3):25–42.
- Dye, C; Bjerke, A; Schmidbauer, N; Mano, S. Measurement of Air Pollution in Indoor Artificial Turf Halls. Norwegian Pollution Control Authority/Norwegian Institute for Air Research, State Programme for Pollution Monitoring. 2006. <u>http://www.isss-</u> <u>sportsurfacescience.org/downloads/documents/SI1HPZNZPS_NILUEngelsk.pdf</u>.
- Consumer Product Safety Commission (CPSC). CPSC Staff Analysis and Assessment of Synthetic Turf Grass Blades. 2008. Available at: <u>http://www.cpsc.gov/PageFiles/104716/turfassessment.pdf</u>.

- Moretto, R. Environmental and Health Evaluation of the Use of Elastomer Granulates (Virgin and From Used Tyres) as Filling in Third-generation Artificial Turf, France, ALIAPUR in partnership with Fieldturf Tarkett and the ADEME (Environmental French Agency). 2007. <u>http://www.aliapur.fr/media/files/RetD_new/Synthetic_turf_</u> <u>Environmental_Study_Report.pdf</u>.
- 33. Bass, JJ; Hintze, DW. Determination of Microbial Populations in a Synthetic Turf System. 2013. *Skyline-The Big Sky Undergraduate Journal*. 1(1):1.
- 34. Keller, M. The fate of methicillin-resistant staphylococcus aureus in a synthetic field turf system. 2013. The University of Toledo Digital Repository: theses and dissertations.
- 35. Vidair, C. Study of Artificial Turf Containing Crumb Rubber Infill Made from Recycled Tires: Measurements of Chemicals and Particulates in the Air, Bacteria in the Turf, and Skin Abrasions Caused by Contact with the Surface. California Department of Resources Recycling and Recovery. 2010. Publication # DRRR-2010-009.
- McNitt, AS; Petrunak, D; Serensits, T. A Survey of Microbial Populations in Infilled Synthetic Turf Fields. Penn State University, College of Agricultural Sciences, Department of Plant Science. 2006. <u>http://plantscience.psu.edu/research/centers/ssrc/research/microbial</u>.

List of Attachments

Attachment 1. Authorizing Legislation Attachment 2. 60-day Federal Register Notice Attachment 2a. Public Comments and Agency Responses **Attachment 3. External Peer Review and Agency Responses** Attachment 4. Forms and Supporting Documents Attachment 4a. Field User Fact Sheet Attachment 4b. Field User Eligibility Screening Script Attachment 4c. Activity 2 Consent, Assent, Permission Forms Attachment 4d. Field User Adult and Adolescent Questionnaire Attachment 4e. Field User Youth and Child Questionnaire Attachment 4f. Exposure Measurement Form Attachment 4g. Phlebotomist Safety Exclusion Questions Form Attachment 5. Privacy Impact Assessment Attachment 6. Research Protocol Attachment 7. CDC IRB Approval Attachment 8. US EPA Human Research Review Approval