Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

OMB Control No. 0923-New

New Information Collection Request

Supporting Statement Part A –

Justification

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Part A. Justification

Goals of the research study: Under the constrained timeline of the *Federal Research Action Plan*, the research study designs associated with this federal collection are necessarily limited in scope and are not intended for nationwide statistical generalizations. The research goals for the 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). While the sample design will not allow for generalization of results to the universe of tire crumb rubber infill and 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, and the tire crumb rubber constituents, exposures, and human activity factors. This investigative pilot 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: 1) providing information on the chemical composition of crumb rubber infill; and 2) 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. By the end of 2016, the agencies anticipate releasing a draft status report that describes the preliminary findings and conclusions of the research through that point in time.

Methods to be used to collect: Activity 1 collections include: 1) collecting native/new tire crumb rubber samples from nine recycling plants located throughout the US; and 2) enrolling 40 facilities with synthetic turf fields with crumb rubber infill (ten facilities located in four US census regions), administering questionnaires, and collecting crumb rubber infill samples from active fields. Activity 2 collections include: 1) enrolling 60 field users, children and youth ages 7-17 and adults, from a sub-set of the 40 enrolled facilities with fields in Activity 1 to administer questionnaires; 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. For Activity 3, 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: For Activity 1, a convenience sample of facilities that have synthetic turf fields, through owner and operator respondents who are knowledgeable about activity patterns, field maintenance, and other procedures affecting exposure to potential chemicals of concern. For Activity 2, a convenience sample of field users (e.g., athletes) who are persons with potential for high exposures to contaminants in synthetic turf. For Activity 3, a sub-set of individuals participating in Activity 2. The study aims to include substantially more fields and 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 action plan, ATSDR and US EPA are co-sponsoring this research study titled *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*. This is a new information collection request (ICR). Given the highly constrained timeline in the action plan, ATSDR is requesting Paperwork Reduction Act (PRA) clearance for 6 months (180 days), in accordance with 5 CFR 1320, *Controlling Paperwork Burdens on the Public*, Section 1320.13 *Emergency Processing*. By the end of November 2016, the agencies anticipate releasing a draft status report that describes the preliminary findings and conclusions of the research through that point in time.

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 February 18, 2016 (Attachment 2), extended the comment period at the public's request for two additional weeks to May 2, 2016, and received and addressed over 80 comments. The agencies' response to public comments is found in Attachment 2a and is further discussed in Section A.8. Additionally, the research protocol was reviewed by three external experts; external peer review comments and the agencies' responses are in Attachment 3.

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

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

This study includes three activities subtitled: *Tire Crumb Rubber Collection and Characterization* (hereafter, Activity 1); and *Field User Exposure Characterization* (hereafter, Activity 2). The specific research objectives are to: 1) identify and characterize constituents of recycled tires used in a convenience sample of artificial turf fields; 2) characterize human exposures to the tire crumb rubber in a convenience sample of field users; and 3) collect biological specimens from users of tire crumb rubber synthetic turf fields to guide future research activities.

All activities will be conducted on a one-time basis. The data will be analyzed by scientists at ATSDR and US EPA and other federal partners 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 in each activity will allow for evaluation of chemical constituents in some crumb rubber infill and 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 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, and the tire crumb rubber constituents, exposures, and human activity factors. This investigative pilot 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 that can be completed in 2016 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. Activity 1 - Tire Crumb Rubber Collection and Characterization

In Activity 1, we will evaluate the manufacturing process and material use patterns to describe the tire crumb manufacturing process, the diversity of the processes, the variability of material blends, and the chemical constituents within the material. ATSDR and EPA will contact selected tire recycling plants manufacturing crumb rubber, in addition to selected synthetic turf facility owners and operators. Outreach to multiple entities will be conducted for recruitment and enrollment, including but not limited to state partners, professional and college athlete organizations, or contacts within the Department of Defense or specific military branches. Additionally, individual municipalities may be contacted directly.

For interested recycling plants, we will provide study fact sheets, determine their eligibility, and obtain their agreement to collect samples (Attachment 4a, 4b, and 4c). Native crumb rubber samples will be collected from tire recycling plants that manufacture crumb rubber (Attachment 4d). No questionnaires will be administered to recycling plants. We will be collecting about twelve pounds of crumb rubber for each plant; however, the collection will occur from three different lots or storage containers (about four pounds per lot or container). The material from the three different lot or storage container at each facility will be analyzed as individual samples.

For interested synthetic turf field facilities with crumb rubber infill, we will provide study fact sheets, determine their eligibility, and obtain their agreement to collect samples (Attachment 4e, 4f, and 4g). We will characterize field use patterns and field maintenance procedures using a structured questionnaire (Attachment 4h). Additionally, facility owners will be asked to allow tire crumb rubber samples collection from each field in order to obtain a better understanding of operating fields based on diverse conditions (Attachment 4i). The total amount of crumb rubber collected will equal approximately six pounds; however, the crumb rubber samples will be collected from seven different locations on the field. This results in a collection of crumb rubber of less than one pound per location. The New York Department of Health estimated a typical field contains between 83 and 120 tons of crumb rubber material.

The samples collected from manufacturers and from the fields will be used to characterize chemical constituents in a variety of crumb rubber infill material, including materials of different ages and weathering patterns. The samples will also be used to conduct laboratory testing to determine bioaccessibility of samples using simulated bodily fluids, including but not limited to gastric fluid, sweat, and saliva. Samples will also be tested for VOC and SVOC emissions in laboratory chamber studies. Microbial characterization will be performed for tire crumb rubbers samples collected from synthetic fields. Specifically, Activity 1 will be conducted to identify key constituents of concern in crumb rubber infill in synthetic turf fields and possibly to evaluate potential cancer and non-cancer toxicity of key constituents using extant toxicity information.

A.2.2. Activity 2 - Field User Exposure Characterization

Activity 2 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 that can be completed in 2016 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.

Activity 2 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. 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 5a, 5b, and 5c). 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 5d). For children ages 7-9 and youth ages 10-12, we will ask the parent/guardian to answer the survey questions (Attachment 5e).

We will conduct a more detailed exposure measurement sub-study on a sub-sample of 45 of the 60 enrolled respondents. We aim to conduct the exposure measurement sub-study among field users at the same fields used in Activity 1. The sub-study will include personal air monitoring and dermal wipe sampling (Attachment 5f).

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.

A.2.3. Activity 3 – Collection of Biological Specimens for a Repository

The goal of Activity 3 is 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.. The future research activities conducted using this biorepository will be guided by the findings of Activity 1 – identification of chemical constituents in a convenience sample of crumb turf samples, the likelihood of attributing exposure to crumb turf use, and hazards associated with those constituents

CDC will ask the 45 individuals recruited for the sub-study that is part of Activity 2 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 5g). The biological specimens will not be analyzed in the current project time frame but will be archived indefinitely for future analysis.

The peer review comment and response document highlighted the plan to archive the biological specimen portion of the proposed protocol, which the peer reviewer identified as a significant limitation to the study's ability to measure true exposure. In its response, CDC acknowledged that the delay to analyze true exposure as measured via the collected biological specimens in this investigation is intentional due to methodological reasons and restrictions on the study's timeline and resources. However, the initial deliverables as indicated in the Federal Research Action Plan are not dependent upon the analysis of biological specimens.

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 both the facility owners and operators and 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 with three main research activities. 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.

Many studies have attempted to characterize chemical constituents of tire crumb rubber material through direct extraction or digestion (Marsili et al., 2014; Celeiro et al., 2014; Llompart et al., 2013; Simcox et al., 2011; Menichini et al., 2011; Highsmith et al., 2009; Mota et al., 2009), leaching experiments (Krüger et al, 2012; Rhodes et al., 2012; Li et al., 2010; NYDEC, 2009;) headspace or off-gassing analysis (Simcox et al., 2011; Nilsson et al., 2008; Incorvia et al., 2007), bioaccessibility testing (Pavilonis et al., 2014; Lioy and Weisel, 2011; Zhang et al., 2008; Cal-OEHHA, 2007; Highsmith et al., 2009), or through other techniques. Many of these studies have examined metal constituents, a modest number have measured VOCs, PAHs and benzothiazole, but relatively few studies have tried to measure or look for the presence or absence of many other organic chemicals potentially associated with tire materials.

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) and the Washington State Department

of Health. 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 four US census regions 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. The Washington State Department of Health's efforts are focused on a cancer incidence study among soccer players residing in the state at the time of diagnosis. However, the cancer incidence study is not designed to determine excess risk of cancer endpoints.

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 questions, if posed to small businesses, will be held to the absolute minimum required for the intended uses of the requested information.

A.5.1. Activity 1 - Tire Crumb Rubber Collection and Characterization

Activity 1 will involve facilities which may be defined as small businesses or small entities.[2] The estimated burden hours for this collection (n=161 hours) represents 48 percent of the total estimated burden hours for all three activities (n=333 hours), as described in Section A.12.

A.5.2. Activities 2 and 3 - Field User Exposure Characterization and Collection of Biological Specimens for Repository

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

[2] Definition from OMB Form 83 I accessed 01/23/2016: A small entity may be (1) a small business which is deemed to be one that is independently owned and operated and that is not dominant in its field of operation; (2) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field; or (3) a small government jurisdiction which is a government of a city, county, town, township, school district, or special district with a population of less than 50,000.

A.6. Consequences of Collecting the Information Less Frequently

Each 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, for Activity 3, 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. Due to the time constraints of the 12-month *Federal Research Action Plan* (status report due in November 2016), the respondents for research activities will be drawn from convenience samples; therefore, the results are not intended to be generalized to the universe of US recyclers, manufacturers, field facilities, or field users. Previous studies have shown that there has been significant issues with obtaining permission to study and sample synthetic turf fields with crumb rubber infill.

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 February 17, 2016, Vol. 81, No. 32, pp. 8201-2 (Attachment 2). The initial end of the public comment period was April 18, 2016, by which ATSDR and US EPA received 31 public comments related to this notice. The CDC Information Collection Review Office (ICRO) received numerous requests for the public comment period to be extended. The agencies agreed to extend the public comment period to May 2, 2016, an additional two weeks, by which an additional 52 comments were received, or a total of 83 public comments. Although

ICRO received numerous requests for a second extension, the agencies declined due to their pressing need to finalize the protocol for IRB review. The agencies also received six additional comments outside of the Federal Docket Management System (FDMS) after May 2, 2016. Two were hardcopies of letters already received electronically. The agencies' response is provided in Attachment 2a.

B. 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*. The activities outlined in the action plan are 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*	*TireCrumbs@epa.gov*
Eric Hooker, MS, DABT	Toxicologist	CPSC	*(301) 987-2516*	*EHooker@cpsc.gov*
Kent Thomas, BSPH	Research Physical Scientist	US EPA	*(919) 541-4651*	*TireCrumbs@epa.gov*

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*	*mzz7@cdc.gov*

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

A.9.1. Activity 1 - Tire Crumb Rubber Collection and Characterization

For Activity 1, no tokens of appreciation will be given to recycling/crumb rubber manufacturing plants that provide native tire crumb samples (Attachment 4d). Additionally, no tokens of appreciation will be given to synthetic turf field facilities that complete the synthetic turf field

questionnaire (Attachment 4g) and provide access to collect the crumb rubber samples (Attachment 4i).

A.9.2. Activities 2 and 3 - Field User Exposure Characterization and Collection of Biological Specimens

For Activities 2 and 3, 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.

For the sub-study, respondents will undergo the exposure measurements component and will receive additional gift cards for the monitoring and biological specimen collection. The maximum received for this portion of the activity is $40, specifically:

- Pre-activity urine and blood collection: $15
- Post-activity, including activity monitoring and blood and urine collection: $25

For the sub-study respondents who also participate in the video portion, respondents will receive an additional gift card ($10) as a token of thanks upon completion of the video activity.

The gift cards for Activities 2 and 3 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 of Appreciation by Level of Collections Completed

Activities 2 and 3 Nested 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 Videography	24	$75

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 6.

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

A.10.1. Activity 1 - Tire Crumb Rubber Collection and Characterization

Although the Privacy Act does not apply to organizations, some confidentiality statutes may apply to organizations, including those that protect confidential business information. The agencies will provide privacy protections to Activity 1 respondents to the extent allowable by law. For example, the identity of the person responding on behalf of the organization may be known to researchers, but this information will not be released as part of the study results and in any agency reports. The information provided will be protected and will not be disclosed to the public to the extent that it satisfies the criteria for exemption under the Freedom of Information Act (FOIA), 5 USC Section 552, and the Trade Secrets Act, 18 USC Section 1905.[3] ATSDR and EPA will protect the information in accordance with its privacy and security policies and procedures. Due to the nature of the questions regarding synthetic turf field maintenance, ATSDR and USEPA will be collecting information from individuals based on their business role only.

The following information in identifiable form (IIF) categories apply to this information collection: name, phone number, and business email address. The access agreement forms, eligibility forms and the questionnaires have questions that involve IIF (Attachments 4b, 4c, 4f, 4g, and 4h). US EPA and/or CDC/ATSDR will maintain personal information within the access agreement forms in a locked file cabinet. All IIF information in the electronic survey

[3] CERCLA Section 104(e)(7)(42 USC 9604(e)(7)) Confidentiality of Information: Provides confidentiality protections for information collected under Section 104 to the extent it is entitled to protection under 18 USC 1905, generally referred to as the Trade Secrets Act.

instruments (eligibility screening and questionnaire) 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.

A.10.2. Activities 2 and 3 - Field User Exposure Characterization and Collection of Biological Specimens

For Activities 2 and 3, 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).[4] 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 5c). 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

[4] 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)

The study protocol (Attachment 7) has been submitted and approved by the CDC IRB (Attachment 8). 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.

A.12. Estimates of Annualized Burden Hours and Costs

The total estimated time burden for the three activities to be conducted under *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill* is 333 hours. Estimated annualized burden hours are presented for each research activity below.

A.12.1. Activity 1 - Tire Crumb Rubber Collection and Characterization

The estimated burden hours for Activity 1 is 161 hours.

- Identified tire recycling/crumb rubber manufacturers will be contacted via telephone to determine interest. The interest telephone script is estimated to take 5 minutes resulting in a burden of 1 hour.
- The native crumb rubber sample collection from the tire recycling/crumb rubber manufacturers is estimated to take 90 minutes resulting in a burden of 14 hours.
- Identified synthetic turf field facility owners/operators will be contacted via telephone to determine interest in study participation and to determine eligibility. The eligibility screening survey is estimated to take 5 minutes resulting in a burden of 6 hours.
- For the estimated time burdens for the synthetic turf field facility owners/operators, the questionnaire detailing standard operating procedures for synthetic turf fields is estimated to take 30 minutes resulting in a burden of 20 hours.
- The synthetic turf field collection of the crumb rubber is estimated to take three hours per field resulting in a burden of 120 hours.

Table A.12.1a: Estimated Annualized Burden Hours for Activity 1

Type of	Form Name	No. of	No. of	Avg. Burden	Total Burden

Respondents		Respondents	Responses per Respondent	per Response (in hrs.)	(in hrs.)
Tire Recycling/Crumb Rubber Manufacturing Plants	Invitation Telephone Script	10	1	5/60	1
	Plant Sampling Collection Form	9	1	90/60	14
Synthetic Turf Field Facilities	Eligibility Screening Script	70	1	5/60	6
	Owner Manager Questionnaire	40	1	30/60	20
	Field Sampling Collection Form	40	1	3	120
Total					161

For the facilities personnel, to estimate the cost of the respondent, the median hourly wage for turf managers ($45) was determined using a document provided by Rutgers University (http://turf-management-jobs.rutgers.edu/turf-management-salary.html).

Table A.12.1.b: Estimated Annualized Burden Costs for Activity 1

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tire Recycling/Crumb Rubber Manufacturing	Invitation Telephone Script	1	$45.00	$45.00
	Plant Sampling Collection Form	14	$45.00	$630.00

~~Plants~~				
Synthetic Turf Field Facilities	Eligibility Screening Script	6	$45.00	$270.00
	Owner Manager Questionnaire	20	$45.00	$900.00
	Field Sampling Collection Form	120	$45.00	$5,400.00
Total				$7,245.00

A.12.2. Activities 2 and 3 - Field User Exposure Characterization and Collection of Biological specimens

For the 60 initial respondents in Activity 2, the eligibility screening is estimated to take 5 minutes resulting in a burden of 5 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 (Activity 3). Parent or guardian respondents will provide permission for their assenting youth or child to provide specimens (Activity 3). 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.

Table A.12.2.a: Estimated Annualized Burden Hours for Activities 2 and 3

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Adult/ Adolescent	Eligibility Screening	36	1	5/60	3

Field Users	Script				
	Adult and Adolescent Questionnaire	36	1	30/60	18
	Exposure Measurement 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	24	1	5/60	2
	Youth and Child Questionnaire	24	1	30/60	12
	Phlebotomist Safety Exclusion Questions Form	18	1	2/60	1
Youth/Child Field Users	Exposure Measurement Form	18	1	3	54
Total					172

For Activities 2 and 3, 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.

Table A.12.2.b: Estimated Annualized Burden Costs for Activities 2 and 3

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adult/ Adolescent Field Users	Eligibility Screening Script	3	$7.25	$21.75
	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	2	$23.23	$46.46
	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				$2,349.62

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

There will be no additional capital and maintenance costs for the three research activities described in this ICR for respondents or record keepers.

A.14. Annualized Cost to the Federal Government

For these three research activities, the annual personnel costs are based on a FTE at GS-13/1 with an estimated 12 full time staff. The estimated average annualized cost of the program is $1,079,660.

- Personnel: $1,059,660 per year.
- Travel: $20,000. 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 $1.80 million. In total, the estimated annual cost to the government is $2.88 million, based on the estimated costs in the *Federal Research Action Plan*.

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 OMB approval. 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. Specifically, by the end of November 2016, the agencies are scheduled to release a draft report that describes the findings and conclusions of the work conducted under this approval and other activities in the *Federal Research Action Plan* through that point in time. 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. For more details, see Table A.16.

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.

Table A.16: Timeline for Activities Investigating Crumb Rubber Infill in Synthetic Turf

Activity	2015 - 2016												
	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Task 1: Federal agency engagement and coordination	X	X	X	X	X	X	X	X	X	X	X	X	
Task 2: Conduct outreach with stakeholders and states		X	X	X	X	X	X						
Task 3: Literature review and key science gap analysis	X	X	X	X	X	X	X	X	X	X	X	X	
Prepare for research													
Peer-reviewed study design	X	X	X	X	X	X							
Quality assurance project plan		X	X	X	X	X	X						
Contracts issuance					X	X	X						
Human subjects approvals							X						
OMB ICR approval	X	X	X	X	X	X	X						
NOTE: Some of the activities in Tasks 4 and 5 require finalized study design, humans subjects approval, and OMB ICR approval													
Task 4: Characterize constituents, emissions, and bioavailability													
a. Evaluate information on tire crumb material			X	X	X	X	X						
b. Laboratory constituent characterization								X	X	X	X		
c. Laboratory bioavailability assessment								X	X	X	X		
d. Obtain extant toxicity information on constituents								X	X	X	X		
Task 5: Characterize exposure under use conditions													
a. Characterize exposure scenarios and activity patterns		X	X	X	X	X	X	X	X				

b. Conduct pilot scale exposure characterization study									X	X	X	X	
c. Develop methods for measuring exposures						X	X	X					
Research report											X	X	X

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.

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List of Attachments