Camcopter S–100, which has been placed in the docket. The S–100 would be considered Risk Class 3.

Operational Considerations

The following operational considerations were evaluated during the development of this document:

1. The S–100 would be used for power transmission line survey operations. It operates in a designated corridor and area within the right-of-way of the power transmission lines and is operationally limited to 100 feet above and laterally within 100 feet of the power line it would be surveying.

2. While there is minimal population exposure within the power transmission line right-of-way, the mission path would cross several public highways and pass in close proximity to several neighborhoods with population densities of less than 950 people per square mile.

3. The S–100 would operate Beyond Visual Line of Sight (BVLOS). BVLOS for this UAS is defined as those operations that do not conform to the definition of Visual Line of Sight (VLOS) in 14 CFR part 107.31 at amendment 107–1.

4. The radio control uplink and downlink would operate within frequencies approved by the Federal Communications Commission (FCC).

5. This S–100 is designed to operate both autonomously and manually by the pilot-in-command (PIC).

6. Minimum crew includes one PIC, one mission specialist, and one mission flight director.

7. The minimum crew would operate only one S–100 at any time.

8. The aircraft would remain within Radio Line of Sight (RLOS) of the control station. RLOS refers to the straight and unobstructed path between the transmitting and receiving antennas.

9. The control station would be ground based.

10. All crew would be FAA certified airmen with current and applicable medical credentials.

11. All crew would successfully complete required crew training.

12. Maintenance personnel would hold appropriate FAA maintenance certificates.

13. Maintenance personnel would complete required maintenance training.

Unresolved Criteria

The FAA's ongoing development of operational criteria will necessitate the incorporation of additional airworthiness criteria into the S–100 and may also necessitate future clarity of the airworthiness criteria published in the *Airworthiness Criteria for the FlightScan Camcopter S–100,* available in the docket. These may include but are not necessarily limited to the following—

1. Command and Control (*) [3]—UAS control and communications link security is a key safety and interoperability requirement in integrating civil UAS into the National Airspace System NAS;

2. Sense and Avoid (SAA) Equipage (*)—SAA systems could serve as a means of compliance with 14 CFR 91.113 right-of-way rules and others. Issues associated with the use of SAA systems to comply with 14 CFR 91 requirements and others, if any, must be identified; and

3. Noise Act Finding (*)—Noise standards have not been developed for UAS.

Proposed Airworthiness Criteria

The FAA has not previously published airworthiness criteria for UAS. The FAA proposes new type certification airworthiness criteria for the FlightScan Camcopter S–100 as found in *Airworthiness Criteria for the FlightScan Camcopter S–100,* Revision 0, dated November 3, 2017. Locate the document at *http://www.regulations.gov* using docket number FAA–2017–1058.

Issued in Kansas City, Missouri, on November 8, 2017.

Pat Mullen,

Manager, Small Airplane Standards Branch, Aircraft Certification Service.

[FR Doc. 2017–24866 Filed 11–15–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 170 and 570

[Docket No. FDA–2017–D–0085]

Best Practices for Convening a Generally Recognized as Safe Panel: Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry entitled ''Best Practices for Convening a GRAS Panel.'' This draft guidance document is intended for any person who is responsible for a conclusion that a substance may be used in food on the basis of the generally recognized as safe (GRAS) provision of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) when that person convenes a panel of experts (''GRAS panel'') to independently evaluate whether the available scientific data, information, and methods establish that the substance is safe under the conditions of its intended use in human food or animal food. This draft guidance provides our current thinking on best practices to identify GRAS panel members who have appropriate and balanced expertise; to take steps to reduce the risk that bias (or the appearance of bias) will affect the credibility of the GRAS panel's output (often called a ''GRAS panel report''), including the assessment of potential GRAS panel members for conflict of interest and the appearance of conflict of interest; and to limit the data and information provided to a GRAS panel to public information (*e.g.,* by not providing the GRAS panel with information such as trade secret information).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on this draft guidance before we issue the final version of the guidance, submit either electronic or written comments by May 15, 2018. For comments related to the collection of information provisions in this draft guidance, submit either electronic or written comments by January 16, 2018.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your

[3] Criteria that have not yet been developed are identified with an asterisk (*).

comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–0085 for ''Best Practices for Convening a GRAS Panel.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.''

Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–200), 5001 Campus Dr., College Park, MD 20740 or to the Office of Surveillance and Compliance (HFV–200), 7519 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: *Regarding substances that would be used in human food:* Paulette M. Gaynor, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1192. *Regarding substances that would be used in animal food:* Geoffrey K. Wong, Center for Veterinary Medicine (HFV–224), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5838. *Regarding the information collection issues:* FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 201(s) of the FD&C Act (21 U.S.C. 321(s)) defines a ''food additive'' as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. Under this definition, a substance that is GRAS under the conditions of its intended use is not a ''food additive'' and is therefore not subject to mandatory premarket review by FDA under section 409 of the FD&C Act (21 U.S.C. 348). In this document, we refer to a person who is responsible for a conclusion that a substance may be used in human food or animal food on the basis of the GRAS provision of the FD&C Act, without premarket review by FDA under section 409 of the FD&C Act, as the ''proponent'' of that substance.

We have established regulations implementing the GRAS provision of section 201(s) of the FD&C Act in part 170 (21 CFR part 170) for human food and in part 570 (21 CFR part 570) for animal food. Those regulations include a voluntary procedure (''GRAS notification procedure'') through which a proponent may notify us of a conclusion that a substance is GRAS under the conditions of its intended use in human food (part 170, subpart E) or animal food (part 570, subpart E). Under the interim pilot program, we have filed and responded to more than 600 GRAS notices for substances intended for use in human food and 18 GRAS notices for substances intended for use in animal food (80 FR 54960 at 54964, August 17, 2016).

In some cases, the process whereby the proponent evaluates whether the available data and information support a conclusion that a substance is GRAS under the conditions of its intended use includes considering the opinion of a ''GRAS panel'' of qualified experts who independently evaluate whether the available scientific data, information, and methods establish that a substance is safe under the conditions of its intended use in human food or animal food. Depending on the outcome of the GRAS panel's analysis, the proponent could either reach a conclusion regarding the safety of the substance under the conditions of its intended use, or be advised of one or more issues (such as gaps in the data and information, or alternative interpretations of the available data and information) that warrant investigation before a conclusion can be drawn about whether the substance is safe under the conditions of its intended use. When the outcome of the GRAS panel's analysis supports the proponent's conclusion that a substance is safe under the conditions of its intended use, in essence the proponent then relies on the members of the GRAS panel to act as a proxy for the larger scientific community knowledgeable about the safety of substances directly or

indirectly added to food and, in so doing, relies on the outcome of the GRAS panel's analysis to support the proponent's conclusion that the safety of the intended use is ''generally recognized'' by qualified experts. Whether a GRAS panel is a sufficient proxy for the larger scientific community depends on a number of factors, such as the subject matter expertise of the members of the GRAS panel and whether the members of the GRAS panel would be considered representative of experts qualified by scientific training and experience to evaluate the safety of the substance under the conditions of its intended use.

A GRAS panel is one mechanism that proponents have used to demonstrate that the safety of a substance under the conditions of its intended use is generally recognized by qualified experts. However, the use of a GRAS panel is not the only mechanism for doing so and the use of a GRAS panel does not necessarily mean that the GRAS criteria have been met (81 FR 54960 at 54974–54975, August 17, 2016).

We are announcing the availability of a draft guidance for industry entitled ''Best Practices for Convening a GRAS Panel.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. This is not a significant regulatory action subject to Executive Order 12866.

This draft guidance document is intended for any proponent who convenes a GRAS panel and provides our current thinking on best practices to identify GRAS panel members who have appropriate and balanced expertise; to take steps to reduce the risk that bias (or the appearance of bias) will affect the credibility of a GRAS panel report, including the assessment of potential GRAS panel members for conflict of interest and the appearance of conflict of interest; and to limit the data and information provided to a GRAS panel to public information (*e.g.,* by not providing the GRAS panel with information such as trade secret information).

II. Paperwork Reduction Act of 1995

This draft guidance contains proposed information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the information collected on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Best Practices for Convening a GRAS Panel (OMB control number 0910—NEW).

Description of respondents: This new collection of information would be performed by those persons (''proponents'') who are responsible for a conclusion that a substance may be used in food on the basis of the GRAS provision of the FD&C Act when such persons convene a GRAS panel to independently evaluate whether the available scientific data, information, and methods establish that the substance is safe under the conditions of its intended use in human food or animal food. The records recommended in this draft guidance would include a one-time information collection burden pertaining to a written GRAS panel policy to govern the assembly and conduct of a GRAS panel. The records recommended in this draft guidance also would include annual information collection burdens pertaining to documenting the application of the written GRAS panel policy to each member of a GRAS panel convened in a given year. Finally, the draft guidance recommends that a GRAS panel provide a written report of its findings; however, we consider that a written GRAS panel report is customary business practice that is already being created by GRAS panels and, thus, we do not estimate an annual information collection burden for the creation of a GRAS panel report.

Analysis of Burden Estimates Resulting from the Recommendation for a Written GRAS Panel Policy: For the purpose of this analysis, we make the conservative assumption that all proponents who document a GRAS conclusion will create a written GRAS panel policy that would apply to GRAS panels convened in the first year that the draft guidance, if finalized, would be in effect as well as to GRAS panels convened in subsequent years. We also assume that these proponents will create a written GRAS panel policy regardless of whether they report the documented GRAS conclusion to FDA in the form of a GRAS notice. Therefore, for the purpose of this analysis we: (1) Calculated the number of proponents who have submitted at least one GRAS notice to FDA and (2) estimated the number of proponents who have documented at least one GRAS conclusion without reporting that documented GRAS conclusion to FDA in the form of a GRAS notice.

Using the data in our inventories of GRAS notices submitted for substances intended for use in human food (Ref. 1) and animal food (Ref. 2) during the time period of April 17, 1997, through September 5, 2017, we calculate that 396 proponents submitted at least one GRAS notice for a substance intended for use in human food, and 15 proponents submitted at least one GRAS notice for a substance intended for use in animal food. During that time period, there were three proponents who had submitted at least one GRAS notice for a substance intended for use in human food and at least one GRAS notice for a substance intended for use in animal food. However, for the purpose of this analysis, we make the conservative assumption that there will be no overlap between proponents who submit GRAS notices for substances intended for use in human food and proponents who submit GRAS notices for substances intended for use in animal food. Therefore, the total number of proponents who have submitted at least one GRAS notice to FDA is 411 (396 proponents + 15 proponents = 411 proponents).

We have very little information about the number of proponents who have documented a GRAS conclusion without reporting that GRAS conclusion to FDA in the form of a GRAS notice. To estimate the number of such proponents, we used a publicly

available database entitled ''Independent GRAS (Generally Recognized As Safe) Conclusion Inventory Database'' (Ref. 3), which is a compilation of the results of a consulting company's search of publicly available information in industry trade journals about documented GRAS conclusions for substances intended for use in human food. The oldest entry is for the year 1995. FDA received the first GRAS notice for substances intended for use in human food in 1998 and, thus, the database covers the entire timeframe during which FDA has been receiving GRAS notices for substances intended for use in human food. As of September 5, 2017, that database recorded that there had been a total of 199 documented GRAS conclusions, with 41 of those documented GRAS conclusions reported to FDA as a GRAS notice and 158 of those documented GRAS conclusions not reported to FDA as a GRAS notice. In contrast, as of September 5, 2017, FDA's inventory of GRAS notices shows that the number of GRAS conclusions reported to FDA during this timeframe was 720, not 41 (Ref. 1). We assume that the reduced number of documented GRAS conclusions that the database recorded as being reported to FDA is due to the mechanism by which the database searches for documented GRAS conclusions (*i.e.,* publications in industry trade journals). For example, there could be less incentive for a business that reports its documented GRAS conclusion to FDA to publicize that GRAS conclusion through industry trade journals, because the business can publicize FDA's response to the GRAS notice in other ways.

The database attributes the 158 documented GRAS conclusions not reported to FDA to 142 different proponents. However, 62 of these proponents have also submitted a GRAS notice to FDA and, thus, we calculate that the database attributes documented GRAS conclusions to 80 proponents who have not submitted a GRAS notice to FDA (142 proponents listed in the database—62 proponents who we already counted because they submitted a GRAS notice to FDA). We also make the conservative assumption that the number of proponents who have documented GRAS conclusions without reporting them to FDA since FDA began receiving GRAS notices is twice as high as recorded in the database—*i.e.,* 160 proponents (80 proponents listed in the database × 2 = 160).

The publicly available database does not record documented GRAS conclusions for substances intended for use in animal food. However, based on the number of annual GRAS notices submitted to FDA in recent years, we previously estimated that the number of annual GRAS notices submitted to FDA for substances intended for use in animal food would be 50 percent of the number of annual GRAS notices submitted to FDA for substances intended for use in human food (*i.e.,* we estimated 50 GRAS notices will be submitted to FDA annually for substances intended for use in human food and that 25 GRAS notices will be submitted to FDA annually for substances intended for use in animal food (OMB control number 0910–0342; 81 FR 54960)). Therefore, for the purpose of this analysis we assume that the number of proponents who have documented GRAS conclusions for substances intended for use in animal food without reporting those GRAS conclusions to FDA is 50 percent of the number of proponents who documented GRAS conclusions for substances intended for use in human food without reporting those GRAS conclusions to FDA—*i.e.,* 80 proponents (160 estimated proponents who have documented GRAS conclusions without reporting those GRAS conclusions to FDA × 0.5 = 80 proponents). We calculate that the total number of proponents who documented GRAS conclusions without reporting those GRAS conclusions to FDA is 240 proponents (160 estimated proponents who have documented GRAS conclusions for substances intended for use in human food + 80 estimated proponents who have documented GRAS conclusions for substances intended for use in animal food = 240 proponents).

To estimate the total number of proponents, we are adding 240 estimated proponents who have not reported their documented GRAS conclusions to FDA to the 411 proponents who have already submitted at least one GRAS notice to FDA for a total of 651 proponents who will document a GRAS conclusion (240 non-reporting proponents + 411 reporting proponents = 651 total proponents). As already stated, for the purpose of this analysis we make the conservative assumption that all of these proponents who document GRAS conclusions (*i.e.,* 651 proponents) will create a written GRAS panel policy. We estimate that it would take 40 hours to create a written GRAS panel policy, including 8 hours to review relevant, publicly available policies (*e.g.,* Refs. 4 and 5) that address conflict of interest and 32 hours to tailor a GRAS panel policy specific to the proponent, using relevant information from such existing policies as appropriate to the needs of the proponent. As shown in table 1, the total one-time burden to create a written GRAS panel policy is 40 hours per proponent × 651 proponents = 26,040 hours. We request comment on our estimate of the total number of proponents and on the hourly burden to create a written GRAS panel policy. There are no estimated capital costs or operating and maintenance costs associated with the information collection for a written GRAS panel policy.

Analysis of Burden Estimates Resulting From the Recommendation for Application of a Written GRAS Panel Policy to GRAS Panel Members: Based on the number of annual GRAS notices submitted to FDA in recent years, we previously estimated that 50 GRAS notices will be submitted to FDA for substances intended for use in human food and that 25 GRAS notices will be submitted to FDA for substances intended for use in animal food (OMB control number 0910–0342; 81 FR 54960), for a total number of 75 GRAS notices submitted to FDA each year. We count each GRAS notice as a single GRAS conclusion, and, for the purpose of this analysis, we assume that a different proponent submits each of these GRAS notices. Therefore, we estimate that the total number of documented GRAS conclusions submitted to FDA on an annual basis is 75 GRAS conclusions and that these GRAS conclusions are submitted by 75 proponents.

We have not previously estimated the annual number of documented GRAS conclusions that are not reported to FDA as a GRAS notice. For the purpose of this analysis, to estimate such GRAS conclusions we used the same database (Ref. 3) that we used to estimate the total number of proponents who document GRAS conclusions without reporting the GRAS conclusions to FDA in the form of a GRAS notice. As already stated, the oldest recorded entry in the database is for the year 1995. However, with the exception of that single entry for 1995, the remaining entries are for the years 2001 and beyond. In addition, the current year (2017) has not reached its end. Therefore, we use 16 years (*i.e.,* from 2001 through 2016) as the number of years covering those documented GRAS conclusions that are not reported to FDA. For the purpose of calculating the annual number of documented GRAS conclusions that are for substances intended for use in human food but not reported to FDA, we estimate that there are 157 such GRAS conclusions (158 documented, unreported GRAS conclusions for

substances intended for use in human food minus 1 GRAS conclusion reported before 2001). We calculate that, on average, the annual number of documented, unreported GRAS conclusions for substances intended for use in human food and recorded in the database is 10 (157 documented, unreported GRAS conclusions/16 years = 9.8 documented, unreported GRAS conclusions per year recorded in the database, rounded up to 10). As with our analysis of the total number of proponents, we conservatively assume that the annual number of documented, unreported GRAS conclusions for substances intended for use in human food could be twice as high as the annual number of documented, unrecorded GRAS conclusions recorded in the database—*i.e.,* 20 documented, unreported GRAS conclusions for substances intended for use in human food each year (10 documented, unreported GRAS conclusions recorded in the database on an annual basis × 2 = 20 documented, unreported GRAS conclusions on an annual basis). As with documented GRAS conclusions that are reported to FDA, we assume that a different proponent is responsible for each documented GRAS conclusion not reported to FDA and, thus, on an annual basis there are 20 proponents who do not report their documented GRAS conclusions for substances intended for use in human food to FDA. As with our analysis of the total number of proponents, we conservatively assume that the annual number of documented, unreported GRAS conclusions for substances intended for use in animal food is 50 percent of the annual number of documented, unreported GRAS conclusions for substances intended for use in human food—*i.e.,* 10 documented, unreported GRAS conclusions for substances intended for use in animal food on an annual basis (20 documented, unreported GRAS conclusions for substances intended for use in human food × 0.5). We therefore calculate that there is a total of 30 documented, unreported GRAS conclusions each year (20 documented, unreported GRAS conclusions for substances intended for use in human food + 10 documented, unreported GRAS conclusions for substances intended for use in animal food). We also calculate that there are 105 proponents who document a GRAS conclusion on an annual basis (75 proponents who report their documented GRAS conclusions to FDA as a GRAS notice + 30 proponents who do not report their documented GRAS conclusions to FDA as a GRAS notice = 105 total proponents).

We have information about the percent of proponents who convene a GRAS panel for a documented GRAS conclusion and also submit a GRAS notice to FDA. During the time period April 17, 1997, through September 5, 2017, on average, 63 percent of proponents who submitted a GRAS notice for a substance intended for use in human food, and 60 percent of proponents who submitted a GRAS notice for a substance intended for use in animal food, convened a GRAS panel. We therefore estimate that, on an annual basis, 32 proponents will convene a GRAS panel and submit a GRAS notice to FDA for substances intended for use in human food (63 percent × 50 proponents = 31.5 proponents; rounded up to 32 proponents), and 15 proponents will convene a GRAS panel and submit a GRAS notice to FDA for substances intended for use in animal food (60 percent × 25 proponents = 15 proponents). We calculate that the total number of proponents who will convene a GRAS panel and submit a GRAS notice to FDA is 47 proponents (32 proponents who submit GRAS notices for substances intended for use in human food + 15 proponents who submit GRAS notices for substances intended for use in animal food = 47 proponents). We also assume that all proponents will document the application of a written GRAS panel policy to each member of the GRAS panel.

We have very little information about the percent of proponents who convene a GRAS panel for a documented GRAS conclusion but do not report their documented GRAS conclusions to FDA as a GRAS notice. For the purpose of this analysis, we make the conservative assumption that all 30 proponents who annually document GRAS conclusions without reporting them to FDA will convene a GRAS panel. Taking into account the estimated number of proponents who convene a GRAS panel and submit a GRAS notice to FDA, and the estimated number of proponents who convene a GRAS panel but do not submit a GRAS notice to FDA, we calculate that the total number of proponents who will convene a GRAS panel and document the application of the written GRAS panel policy to each member of a GRAS panel on an annual basis is 77 proponents (47 proponents who submit GRAS notices to FDA+ 30 proponents who do not submit GRAS notices = 77 proponents).

Based on the recommendations in the draft guidance, if finalized, we assume that all GRAS panels will include at least 3 panel members (with expertise in chemistry or biochemistry, toxicology, and exposure assessment) and that some GRAS panels will include as many as 6 panel members with expertise that reflects the physical, chemical, and biological properties of the substance and the scientific questions that arise in relation to the conditions of its intended use. We assume that a GRAS panel will include 5 panel members on average. We also assume that the proponent will reject at least one individual with applicable expertise due to a financial conflict of interest or the appearance of a financial or non-financial conflict of interest and, thus, that 77 proponents will document the application of the written GRAS panel policy to 6 individual GRAS panel members, for a total of 462 documentations by proponents of the application of the written GRAS panel policy (77 proponents × 6 individual panel members = 462 documentations). As shown in table 2, we estimate that it will take 16 hours to document the application of the written GRAS policy to each panel member, for a total of 7,392 hours (462 documentations × 16 hours per documentation = 7,392 hours). As shown in table 3, we assume that all 462 individuals who are being considered as members of a GRAS panel will each need 4 hours to provide applicable information to the proponent, for a total of 1,848 hours (462 individuals × 4 hours per individual = 1,848 hours).

There are no estimated capital costs or operating and maintenance costs associated with this information collection for the application of a written GRAS panel policy to individuals being considered as members of a GRAS panel.

TABLE 1—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

Recommendation	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
Written GRAS panel policy	651	1	651	40	26,040

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Recommendation	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
Application of written GRAS panel policy to GRAS panel members	77	6	462	16	7,392

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Recommendation	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
Information provided by potential GRAS panel members to the proponents of GRAS conclusions	462	1	462	4	1,848

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

IV. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA (2017). GRAS Notices. Available at *https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices.*
2. FDA (2017). Current Animal Food GRAS Notices Inventory. Available at *https://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm.*
3. AIBMR Life Sciences, Inc. (2017). Independent GRAS (Generally Recognized As Safe) Conclusion Inventory Database. Available at *http://aibmr.com/natural-products-industry-compliance-consultation/gras-generally-recognized-as-safe-safety-studies/.*
4. Institute of Medicine (2009). Full Report. *Conflict of Interest in Medical Research, Education, and Practice.* National Academies Press, 500 5th Street NW., Lockbox 285, Washington, DC 20055. Available at *https://www.nap.edu/catalog/12598/conflict-of-interest-in-medical-research-education-and-practice.*
5. The National Academies of Sciences, Engineering, and Medicine (2003). *Conflicts of Interest Policy for Committees Used in the Development of Reports.* The National Academies Press, 500 5th Street NW., Washington, DC 20001. Available at *http://www.nationalacademies.org/coi/.*

Dated: November 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24845 Filed 11–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

[COE–2017–0003]

Establishment of a Permanent Restricted Area for U.S. Coast Guard Yard, Baltimore, Maryland, in Curtis Creek and Arundel Cove

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Corps of Engineers is proposing to establish a permanent restricted area for the U. S. Coast Guard in waters of Curtis Creek and Arundel Cove located in Baltimore, Maryland. The establishment of the restricted area is necessary to reflect the current security needs at U. S. Coast Guard Yard (CG Yard), Baltimore, Maryland, including the protection of Coast Guard-wide military assets. The CG Yard is the Coast Guard's only shipyard and its largest industrial facility. It performs major ship, electronics, and heavy weapons overhaul, repair, and manufacture. The CG Yard is also the host command for various Coast Guard commands supporting local and nationwide Coast Guard missions.