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 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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–2016–D–3401 for ''Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition; Draft Guidance for Industry.'' 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 Division of Dockets Management 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.'' We will review this copy, including the claimed confidential information, in our 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 Division of Dockets Management. 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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paula R. Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2579.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 23, 2016 (81 FR 84516), we published a notice announcing the availability of a draft guidance entitled ''Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition.'' The draft guidance explains the scientific review approach we plan to use for evaluating scientific evidence submitted to us in citizen petitions to determine whether a particular isolated or synthetic non-digestible carbohydrate that is added to food should be added to our definition of ''dietary fiber'' that is found in the Nutrition and Supplement Facts label final rule, which appeared in the **Federal Register** of May 27, 2016 (81 FR 33742). Only those isolated or synthetic non-digestible carbohydrates that meet the definition can be declared as a dietary fiber on a Nutrition and Supplement Facts label. We provided a 60-day comment period that was scheduled to close on January 23, 2017.

Elsewhere in this issue of the **Federal Register**, we have published a notice to reopen the comment period for a related notice that appeared in the **Federal Register** of November 23, 2016 (81 FR 84595). We requested scientific data, information and comments in the related November 23, 2016, notice to help us evaluate the potential beneficial physiological effects on human health of 26 specific isolated or synthetic non-digestible carbohydrates that are added to food so that we may determine whether any of them should be added to our definition of dietary fiber in our Nutrition Facts and Supplement Facts label final rule. The November 23, 2016, notice also announced the availability of a document entitled ''Science Review of Isolated and Synthetic Non-Digestible Carbohydrates,'' which summarizes a scientific literature review that we conducted of clinical studies associated with the 26 specific isolated or synthetic non-digestible carbohydrates. The original comment period for this notice closed on January 9, 2017.

We have received requests to extend the comment period for the isolated or synthetic non-digestible carbohydrates draft guidance. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful comments to the draft guidance.

We have considered the requests and are extending the comment period for the draft guidance until February 13, 2017. We believe that this extension allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance. The extended comment period deadline February 13, 2017, for the draft guidance also coincides with the reopened comment period for our related request for scientific data, information, and comments for the November 23, 2016, notice.

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00724 Filed 1–12–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 121

[Public Notice: 9852]

Notice of Inquiry; Request for Comments Regarding United States Munitions List Category XII

AGENCY: Department of State.

ACTION: Notice of Inquiry, request for comments.

SUMMARY: The Department of State requests comments from the public regarding recent revisions to Category XII of the United States Munitions List (USML). In light of the ongoing transition of the USML to a more ''positive list'' pursuant to the President's Export Control Reform (ECR)

initiative, the Department requests that the public comment on (1) alternatives to controls on certain items when ''specially designed for a military end user,'' (2) the scope of the control in paragraph (b)(1), and (3) certain technical parameters that the Department is evaluating to replace ''specially designed'' controls.

DATES: The Department of State will accept comments on this Notice of Inquiry until March 14, 2017.

ADDRESSES: Interested parties may submit comments by one of the following methods:

- *Email: DDTCPublicComments@state.gov* with the subject line, ''Request for Comments Regarding USML Category XII.''
- *Internet:* At *www.regulations.gov,* search for this notice using its docket number, DOS–2017–0002.

Comments submitted through *www.regulations.gov* will be visible to other members of the public; the Department will publish all comments on the Directorate of Defense Trade Controls Web site (*www.pmddtc.state.gov*). Therefore, commenters are cautioned not to include proprietary or other sensitive information in their comments.

FOR FURTHER INFORMATION CONTACT: Mr. C. Edward Peartree, Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663–2792; email *DDTCPublicComments@state.gov.* ATTN: Request for Comments Regarding USML Category XII.

SUPPLEMENTARY INFORMATION: On December 10, 2010, the Department provided notice to the public of its intent, pursuant to the ECR initiative, to revise the USML to create a ''positive list'' that describes controlled items using, to the extent possible, objective criteria rather than broad, open-ended, subjective, or design intent-based criteria (see 75 FR 76935). As a practical matter, this meant revising USML categories so that, with some exceptions, the descriptions of defense articles that continued to warrant control under the USML did not use catch-all phrases to control unspecified items. As a general matter, the defense articles that warranted control under the USML were those that provided the United States with a critical military or intelligence advantage. All other items were to become subject to the Export Administration Regulations. Since that time, the Department has published final rules setting forth revisions for eighteen USML categories, each of which has been reorganized into a uniform and more positive list structure.

The advantage of revising the USML into a more positive list is that its controls can be tailored to satisfy the national security and foreign policy objectives of the U.S. government by maintaining control over those defense articles that provide a critical military or intelligence advantage, or otherwise warrant control under the International Traffic in Arms Regulations (ITAR), without inadvertently controlling items in normal commercial use. This approach, however, requires that the lists be regularly revised and updated to account for technological developments, practical application issues identified by exporters and reexporters, and changes in the military and commercial applications of items affected by the list. In addition, the USML and the Commerce Control List require regular revision in order to ensure that they satisfy the national security and foreign policy objectives of the reform effort, which are to (i) improve interoperability of U.S. military forces with allied countries, (ii) strengthen the U.S. industrial base by, among other things, reducing incentives for foreign manufacturers to design out and avoid U.S.-origin content and services, which ensures continued U.S. visibility and control, and (iii) allow export control officials to focus government resources on transactions that pose greater concern.

Comments on Specially Designed for a Military End User Parameters: On October 12, 2016, the Department published a final rule amending USML Category XII, effective December 31, 2016 (81 FR 70340). In the final rule, the Department adopted control text in seven subparagraphs that controls specific items when they are specially designed for a military end user. The term military end user is defined in the new Note to Category XII, as the national armed services (army, navy, marine, air force, or coast guard), national guard, national police, government intelligence or reconnaissance organizations, or any person or entity whose actions or functions are intended to support military end uses. As the Note further states, an item is not specially designed for a military end user if it was developed for both military and non-military end users, or if the item was created for no specific end user. The Note also provides that contemporaneous documents are required to support the design intent; otherwise, use by a military end user establishes that the item is specially designed for a military end user.

As stated in the final rule, the Department adopted this control based on original design intent because the Department and its interagency partners cannot yet articulate objective technical criteria that would establish a bright line between military and commercial and civil systems. The Department is soliciting additional public input, asking for suggested control parameters for these seven entries in the final rule:

1. (b)(6) Light detection and ranging (LIDAR), laser detection and ranging (LADAR), or range-gated systems, specially designed for a military end user.

2. (c)(1) Binoculars, bioculars, monoculars, goggles, or head or helmet-mounted imaging systems (including video-based articles having a separate near-to-eye display), as follows:

(iii) Having an infrared focal plane array or infrared imaging camera, and specially designed for a military end user.

3. (c)(3) Electro-optical reconnaissance, surveillance, target detection, or target acquisition systems, specially designed for articles in this subchapter or specially designed for a military end user.

4. (c)(4) Infrared search and track (IRST) systems having one of the following: (ii) Specially designed for a military end user.

5. (c)(5) Distributed aperture systems having a peak response wavelength exceeding 710 nm specially designed for articles in this subchapter or specially designed for a military end user.

6. (c)(6) Infrared imaging systems, as follows:

(viii) Gimbaled infrared systems, as follows:

(B) Specially designed for articles in this subchapter or specially designed for a military end user.

and

7. (c)(7) Terahertz imaging systems as follows: (ii) Specially designed for a military end user.

Comments on Scope of Paragraph (b)(1): Paragraph (b)(1) includes all laser target designators and coded target markers that can mediate the delivery of ordnance to a target. This includes a laser target designator or coded target marker that may also be used for other purposes, including battlefield target handoff or communication of battlefield intelligence information. The Department requests that the public comment on this provision.

Comments to Assist with the Evaluation of Potential Control Parameters: The Department is also evaluating several potential parameters. The Department is requesting that the public comment on these parameters to aid in its evaluation. Specifically, the Department requests comment on

whether any civil or commercial items are described by the following parameters, including items for which civil or commercial use is anticipated in the next five years:

A. Free-space laser communication systems specially designed for articles in this subchapter.

B. Binoculars, bioculars, monoculars, goggles, or head or helmet-mounted imaging systems (including video-based articles having a separate near-to-eye display), having any of the following:

(i) A dynamically gain modulated image intensifier tube incorporating a GaAs, GaInAs, or other III–V semiconductor photocathode with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm;

(ii) An image intensifier tube incorporating a photocathode with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm and incorporating a focal plane array in the tube vacuum space;

(iii) Fusing outputs of multiple infrared focal plane arrays each having a peak response at a wavelength greater than 1,000 nm;

(iv) An infrared focal plane array with a peak response in the wavelength range exceeding 1,000 nm but not exceeding 2,500 nm with a total noise floor less than 75 electrons at an operating temperature of 300 K; or

(v) An infrared focal plane array with a peak response in the wavelength range exceeding 7,500 nm, and a laser illuminator or pointer.

C. Weapon sights (*i.e.,* with a reticle), aiming or imaging systems (*e.g.,* clip-on), specially designed to mount to a weapon or to withstand weapon shock or recoil, with or without an integrated viewer or display, and also incorporating or specially designed to incorporate any of the following:

(i) An image intensifier tube having a multi-alkali photocathode with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm and a luminous sensitivity exceeding 350 microamps per lumen;

(ii) An image intensifier tube having a GaAs, GaInAs, or other III–V semiconductor photocathode, with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm; or

(iii) An image intensifier tube having a photocathode with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm and a focal plane array in the tube vacuum space.

D. Infrared imaging systems, as follows: Mobile reconnaissance, mobile scout, or mobile surveillance systems, that provide real-time target geolocation at ranges greater than 3 km (*e.g.,* LRAS3, CIV, HTI, SeeSpot, MMS).

E. Infrared imaging systems, as follows: Gimbaled infrared systems (*e.g.,* T-bar, yoke, ball turrets, or pods), as follows and specially designed parts and components therefor:

(i) Having a root mean square (RMS) stabilization better (less) than 25 microradians and incorporating an infrared camera having a peak response at a wavelength exceeding 1,000 nm with an optical angular resolution (*i.e.,* detector instantaneous field-of-view) of 25 microradians or less;

(ii) Having an RMS stabilization better (less) than 25 microradians for any payload having any dimension of 15 inches or greater; or

(iii) Specially designed for articles in this subchapter or specially designed for a military end user.

F. Image intensifier tubes having all the following, and specially designed parts and components therefor:

(i) A peak response in the wavelength range exceeding 400 nm but not exceeding 1,050 nm;

(ii) A multi-alkali photocathode with a luminous sensitivity of 1,300 microamps per lumen or greater; and

(iii) A limiting resolution of 64 line pairs per millimeter or greater.

G. Image intensifier tubes having all of the following, and specially designed parts and components therefor:

(i) A peak response in the wavelength range exceeding 400 nm but not exceeding 1,050 nm;

(ii) A GaAs, GaInAs, or other III–V compound semiconductor photocathode having a luminous sensitivity of 1,800 microamps per lumen or greater; and

(iii) A limiting resolution of 57 line pairs per millimeter or greater.

H. Image intensifier tubes having all of the following, and specially designed parts and components therefor:

(i) A peak response in the wavelength range exceeding 1,050 nm but not exceeding 2,000 nm; and

(ii) A GaAs, GaInAs, or other III–V compound semiconductor photocathode having a radiant sensitivity of 10 milliamps per watt or greater.

I. Infrared focal plane arrays or dewars specially designed for optical augmentation reduction.

J. Infrared focal plane array dewar assemblies with peak response in the wavelength range greater than 3,000 nm but not exceeding 14,000 nm, and having a variable aperture mechanism.

K. Infrared focal plane arrays having all of the following:

(i) A peak response in the wavelength range exceeding 710 nm but not exceeding 1,100 nm;

(ii) A non-binned pixel pitch of 10 microns or greater;

(iii) More than 1,024 detector elements in any direction; and

(iv) Total noise of 3 electrons or less at an input light level of 1 millilux, in a binned or non-binned operating mode, and measured at an ambient operating temperature of 300 K.

L. Infrared focal plane arrays having greater than 81,920 but not exceeding 327,680 detector elements, a peak response in the wavelength range 1,100 nm but not exceeding 1,700 nm, and any of the following:

(i) Noise equivalent irradiance less than 829 million photons per centimeter squared per second;

(ii) Readout integrated circuits capable of pulse interval modulation decoding or pulse repetition frequency decoding (*e.g.,* an asynchronous detector read out integrated circuit, frame rates windowed or non-windowed greater than 2,000 Hz); or

(iii) Temperature dependent non-uniformity correction (*e.g.,* without the use of a temperature stabilization)

Note: Noise equivalent irradiance is defined as a ratio with the numerator comprised of the focal plane noise floor in units of electrons at a focal plane array temperature of 300 K and the denominator as the multiplied value of detector area in square centimeters, spectral quantum efficiency at 1,550 nm, and an integration time of 0.032 seconds.

M. Infrared focal plane arrays having greater than 327,680 detector elements, a peak response in the wavelength range exceeding 1,100 nm but not exceeding 1,700 nm, and any of the following:

(i) Noise equivalent irradiance less than 1.54 billion photons per centimeter squared per second;

(ii) A readout integrated circuits capable of pulse interval modulation decoding or pulse repetition frequency decoding (*e.g.,* an asynchronous detector read out integrated circuit, frame rates windowed or non-windowed greater than 2,000 Hz); or

(iii) Temperature dependent non-uniformity correction (*e.g.,* without the use of temperature stabilization)

Note: Noise equivalent irradiance is defined as a ratio with the numerator comprised of the focal plane noise floor in units of electrons at a focal plane array temperature of 300 K and the denominator as the numerator to the multiplied value of detector area in square centimeters, spectral quantum efficiency at 1,550 nm, and an integration time of 0.032 seconds.

N. Infrared focal plane arrays having greater than 327,680 detector elements, a peak response in the wavelength range exceeding 1,700 nm but not exceeding 3,000 nm, and any of the following:

(i) Readout integrated circuits capable of pulse interval modulation decoding

or pulse repetition frequency decoding (*e.g.* an asynchronous detector read out integrated circuit, frame rates windowed or non-windowed greater than 2,000 Hz);

(ii) A total noise floor less than 75 electrons at an operating temperature of 300 K; or

(iii) A detector pitch less than or equal to 20 microns.

O. Infrared focal plane arrays having an internal quantum efficiency exceeding 10 percent anywhere in the wavelength range exceeding 3,000 nm but not exceeding 7,500 nm and any of the following:

(i) A detector pitch less than 12.5 microns; or

(ii) More than 1,331,200 detector elements.

P. Infrared focal plane arrays having a peak response in the wavelength range exceeding 7,500 nm but not exceeding 30,000 nm, and all of the following:

(i) A detector element of the photon, not thermal, type;

(ii) A detector pitch less than or equal to 30 microns; and

(iii) Greater than or equal to 262,144 detector elements.

Q. Infrared focal plane arrays having a peak response in the wavelength range exceeding 7,500 nm but not exceeding 14,000 nm and all of the following:

(i) A detector element of the photon, not thermal, type;

(ii) Greater than 300 detector elements; and

(iii) Time delay integration of detector elements.

R. Microbolometer focal plane arrays having an unfiltered response in the wavelength range exceeding 7,500 nm but not exceeding 14,000 nm and any of the following:

(i) Vacuum packaged and specially designed to withstand weapon shock; or

(ii) Greater than 328,000 detector elements with a detector pitch less than or equal to 14 microns.

S. Infrared focal plane arrays specially designed to provide distinct outputs corresponding to more than one spectral band, and having all the following:

(i) Multiple spectral bands with a photo-response in the wavelength range exceeding 1,100 nm but not exceeding 14,000 nm; and

(ii) A detector element pitch less than 50 microns.

T. Digital low-light-level sensors incorporating a photocathode and a focal plane array within the vacuum space, with a peak response in the wavelength range exceeding 400 nm but not exceeding 2,000 nm, and having any of the following:

(i) A photocathode with a luminous sensitivity greater than 1,800 microamps per lumen; or

(ii) Greater than 2,040,000 focal plane array detector elements.

U. Analog readout integrated circuits specially designed for articles in this subchapter.

and

V. Digital readout integrated circuits specially designed for focal plane arrays having a peak spectral response in the wavelength band exceeding 1,100 nm but not exceeding 30,000 nm, a digital signal output, and any of the following:

(i) Dynamic range greater than 54 dB; or

(ii) Pixel read-out rate greater than 540 million bits per second.

The Department will review all comments from the public. If a rulemaking is warranted based on the comments received, the Department will respond to comments received in a proposed rulemaking in the **Federal Register**.

C. Edward Peartree,

Office Director, Defense Trade Controls Policy, Bureau of Political-Military Affairs, Department of State.

[FR Doc. 2017–00651 Filed 1–12–17; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2015–1113]

RIN 1625–AA00

Safety zone; Tennessee River, Mile 446.0 to 454.5

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a safety zone for all waters of the Tennessee River, beginning at mile marker 446.0 and ending at mile marker 454.5 during periods of high water flow. High water flow is determined by flow rates that have reached or exceeded 100,000 cubic feet per second at Chickamauga lock and dam on the Tennessee River at mile marker 471.0. This proposed safety zone is necessary to provide safety for mariners transiting on the Tennessee River during periods of high water flow. Entry into this area will be prohibited unless specifically authorized by the Captain of the Port Ohio Valley or designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before January 30, 2017.

ADDRESSES: You may submit comments identified by docket number USCG–2015–1113 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Petty Officer Ashley Schad, MSD Nashville, Nashville, TN, at 615–736–5421 or at *Ashley.M.Schad@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
E.O. Executive order
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Captain of the Port Ohio Valley is proposing to establish a safety zone for all waters of the Tennessee River, from mile 446.0 to 454.5 during periods of high water flow. This proposed safety zone is necessary to provide safety for mariners transiting on the Tennessee River during periods of high water flow. There have been temporary final rules issued in the past establishing a safety zone on the Tennessee River beginning at mile marker 446.0 and ending at mile marker 454.5 when flow rates reached or exceeded 100,000 cubic feet per second at Chickamauga lock and dam. Examples of these previous temporary final rules were published under docket numbers USCG–2013–0025 and USCG–2011–1148. This proposed rulemaking is also necessary to more efficiently effect necessary safety measures during emergent high water events in the future by reducing administrative burden and the amount of paperwork required for multiple individual rulemakings. The Tennessee River beginning at mile marker 446.0 and ending at 454.5 poses a navigational hazard during periods of high water flow. A high water flow determination for this area is established when flow rates reach or exceed 100,000 cubic feet per second at Chickamauga lock and dam on the Tennessee River at mile marker 471.0. The Captain of the Port Ohio Valley has determined that additional safety measures are necessary to protect all mariners during periods of high water flow. Therefore, the Coast Guard