DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 170, 177, and 189

[Docket No. FDA–2015–F–0537]

Natural Resources Defense Council et al.; Denial of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; denial of petition.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is denying a petition, submitted by the Natural Resources Defense Council, Center for Food Safety, Clean Water Action, Children's Environmental Health Network, Center for Science in the Public Interest, Breast Cancer Fund, Center for Environmental Health, Environmental Working Group, and Improving Kids' Environment, requesting that we revoke the Threshold of Regulation (TOR) exemption No. 2005–006 to no longer exempt from our food additive regulations the use of sodium perchlorate monohydrate as a conductivity enhancer in antistatic agents for use in finished articles in contact with dry foods; issue a new FDA regulation to prohibit the use of perchlorates in antistatic agents for use in food-contact articles; and amend our food additive regulations to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers.

DATES: This *notification* is effective May 4, 2017; except as to any provisions that may be stayed by the filing of proper objections. See Section VI of this document for information on the filing of objections. Submit either electronic or written objections and requests for a hearing by June 5, 2017. Late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of June 5, 2017. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing identified by Docket No. FDA–2015–F–0537, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, 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 objection 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 objections submitted to the Division of Dockets Management, FDA will post your objection, 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–2015–F–0537 for ''Natural Resources Defense Council et al.; Denial of Food Additive Petition.'' Received objections, those filed in a timely manner (see **DATES**), will be placed in the docket, and except for those submitted as ''Confidential Submissions,'' publically 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 an objection with confidential information that you do not wish to be made publicly available, submit your objections 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or objections 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: Hui-Chen (Anita) Chang, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1161.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a document published in the **Federal Register** of March 16, 2015 (80 FR 13508), we announced that we filed a food additive petition (FAP 4B4808) (''petition'') submitted by the Natural Resources Defense Council, 1152 15th St. NW., Suite 300, Washington, DC 20005; the Center for Food Safety, 303 Sacramento St., Second Floor, San Francisco, CA 94111; Clean Water Action, 144 I St. NW., Suite 400, Washington, DC 20005; the Center for Science in the Public Interest, 1220 L St. NW., Suite 300, Washington, DC 20005; Children's Environmental Health Network, 110 Maryland Ave. NE., Suite 402, Washington, DC 20002; the Breast Cancer Fund, 1388 Sutter St., Suite 400, San Francisco, CA 94109–5400; the Center for Environmental Health, 2201 Broadway, Suite 302, Oakland, CA 94612; Environmental Working Group, 1436 U St. NW., Suite 100, Washington,

DC 20009; and Improving Kids' Environment, 1915 West 18th St., Indianapolis, IN 46202 (collectively, ''petitioners''). In the March 2015 document, we requested comments on the petition under § 189.1(c) (21 CFR 189.1(c)). The petition included submissions dated July 31, 2014, October 15, 2014, and December 5, 2014. The October 15, 2014, submission included a resubmission of the entire July 31, 2014, original petition with the inclusion of some additional information. The December 5, 2014, submission contained additional information to that provided in the October 15, 2014, submission. Any references to specific parts of the petition are to the October 15, 2014, submission while specific references to the December 5, 2014, submission will refer to the date of that document.

The petition asked FDA to take three separate regulatory actions: (1) Revoke its 2005 approval of TOR exemption No. 2005–006 allowing as much as 1.2 percent sodium perchlorate monohydrate in dry food packaging; (2) issue a new § 189.301 (21 CFR 189.301) prohibiting the use of perchlorate as a conductivity enhancer in the manufacture of antistatic agents to be used in food contact articles; and (3) remove potassium perchlorate as an allowed additive in sealing gaskets for food containers in existing § 177.1210 (21 CFR 177.1210). For accuracy, we will refer to the petition's second request as a request to issue a new regulation under part 189 because a regulation already exists at § 189.301. The petition asserted that the allowed food-contact uses of perchlorate are not safe because there is no longer a reasonable certainty that the perchlorate is not harmful under the intended conditions of use considering: (1) The probable consumption of perchlorate; (2) the cumulative effect of perchlorate after taking into account pharmacologically-related substances, such as thiocyanate and nitrate, in the diet; and (3) additional safety factors necessary to protect the developing brain of fetuses and infants from irreversible harm. The petition also asserted that new exposure data are available that support the requested revocation of TOR exemption No. 2005–006.

Both food contact substances that are the subject of the petition—sodium perchlorate monohydrate and potassium perchlorate—belong to a class of chemicals termed ''perchlorates.'' Perchlorates are both naturally-occurring and man-made chemicals with a wide variety of industrial and some medical applications. Perchlorates are ionic salts that contain the perchlorate anion (chemical structure ClO_4^-). In this notification, the term ''perchlorates'' refers to the class of chemicals while the term ''perchlorate'' refers to the perchlorate ion.

II. Background

A. Statutory and Regulatory Background

The petition asked FDA to take actions related to three different types of FDA regulations.

1. Food Additive Regulation

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorizes us to regulate ''food additives'' (see section 409(a) of the FD&C Act (21 U.S.C. 348(a)). The FD&C Act defines ''food additive,'' in relevant part, as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component of food (see section 201(s) of the FD&C Act (21 U.S.C. 321(s))). Food additives can include both substances added directly to food and ''food contact substance[s]'' (*i.e.,* substances intended for use in materials that come into contact with food, for instance in food packaging or manufacturing, but which are not intended to have any technical effect in the food (see § 170.3(e)(3) (21 CFR 170.3(e)(3))). Food additives are deemed unsafe and prohibited except to the extent that we approve their use (see, *e.g.,* section 301(a) and (k) (21 U.S.C. 331(a) and (k)) and 409(a) of the FD&C Act).

The FD&C Act provides a process through which persons who wish to use a food additive may submit a petition proposing the issuance of a regulation prescribing the conditions under which the additive may be safely used (see section 409(b)(1) of the FD&C Act). Such a petition is referred to as a ''food additive petition.'' When we conclude that a proposed use of a food additive is safe, we issue a regulation called a ''food additive regulation'' authorizing a specific use of the substance.

The specific food additive regulation at issue in the petition, § 177.1210, lists substances allowed as indirect additives (also called food contact substances) in closures with sealing gaskets for food containers. Potassium perchlorate is one of the listed substances authorized for this use under § 177.1210.

The FD&C Act provides that we must by regulation prescribe the procedure by which a food additive regulation may be amended or repealed (see section 409(i) of the FD&C Act). Our regulation specific to the administrative actions for food additives provides that the Commissioner of Food and Drugs (the Commissioner), on his own initiative or on the petition of any interested person, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive (see § 171.130(a) (21 CFR 171.130(a))). Our regulation, at § 171.130(b), further provides that any such petition must include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal.

FDA has issued administrative regulations for food additive petitions in part 171. These regulations apply to food additive petitions requesting either that we authorize the new use of a food additive or that we amend or repeal an existing food additive regulation.

2. TOR Exemption

The food additive petition process generally applies to substances used in food packaging or processing when the proposed use will cause the substance to become part of the food at a level that exceeds a minimum ''threshold of regulation'' (see § 170.39 (21 CFR 170.39)). Our determination that a use of a substance is at or below the ''threshold of regulation'' is referred to as a ''threshold of regulation'' exemption, or a TOR exemption. Regardless of whether the use of a substance is at or below the threshold of regulation, we reserve the right to apply the food additive petition process in those cases in which available information establishes that the proposed food-contact use may pose a public health risk (see § 170.39(b)).

We established the procedures set forth in § 170.39 to exempt certain substances used in food-contact articles (*e.g.,* food-packaging (such as a cereal bag) or food-processing equipment) that migrate or may be expected to migrate into food at negligible levels from regulation as a food additive. Eligible substances must become a component of food at levels that are at or below the threshold of regulation, must not have been shown to cause cancer in humans or animals or be suspected carcinogens, and must meet other criteria in § 170.39. If we determine the criteria are met, we inform the requestor by letter that the intended use of a substance in food-contact articles is exempt from regulation as a food additive. Therefore, when we issue a TOR exemption, the intended use of the substance does not require a regulation authorizing its food

additive use under section 409 of the FD&C Act (also referred to as a ''listing regulation'') or food additive petition (see §§ 170.3(e)(2) and 171.8). We issued TOR exemption No. 2005–006 in 2005. We maintain a list of TOR exemptions on our Web site (Ref. 1).

Our regulations provide that if we receive significant new information that raises questions about the dietary concentration or the safety of a substance that is the subject of a TOR exemption, we may reevaluate the substance (see § 170.39(g)). Our regulations, at § 170.39(g), state that if we tentatively conclude that the available information no longer supports an exemption for the use of the food-contact material from the food additive regulations, we will notify any persons that requested an exemption for the substance of our tentative decision and will provide them with an opportunity to show why the use of the substance should not be regulated under the food additive provisions of the FD&C Act. If the requestors fail to adequately respond to the new evidence, we notify them that further use of the substance in question for the particular use will require a food additive regulation (see § 170.39(g)). Thus, anyone who seeks to use such substance as a food additive would need to submit a food additive petition seeking such a regulation or obtain authorization through a food contact notification. We also notify other manufacturers, by means of a notice published in the **Federal Register**, of our decision to revoke a TOR exemption issued for a specific use of a substance in a food-contact article (see § 170.39(g)).

3. Regulation Under Part 189

Our regulations at § 189.1(a) provide that ''food ingredients'' may be prohibited from uses in human food based on a determination that the food ingredients present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human food. Additionally, § 189.1(c) provides that the Commissioner, either on his own initiative or on the petition of any interested person, may publish a proposal to establish, amend, or repeal a regulation under this section on the basis of new scientific evaluation or information. We established part 189 to: (1) Provide, for reference purposes, a partial listing of substances prohibited from use in human food and (2) create an administrative process through which we can prohibit by rulemaking the use of substances in human foods because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human foods (see 39 FR 34172, September 23, 1974).

B. Abandonment of Use of Potassium Perchlorate Authorized Under 21 CFR § 177.1210

In a document published in the **Federal Register** on June 30, 2016 (81 FR 42585), we announced that we filed a food additive petition (FAP 6B4816) (''abandonment petition'') that proposed that we amend § 177.1210 to no longer provide for the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers because the use has been intentionally and permanently abandoned. Elsewhere in this issue of the **Federal Register**, we have published a final rule concluding that the use of potassium perchlorate authorized under § 177.1210 has been permanently and completely abandoned. The final rule amends § 177.1210 to no longer authorize the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers.

Because the final rule issued in response to the abandonment petition removes potassium perchlorate as an allowed additive in sealing gaskets for food containers—thereby taking the third action requested in the petition—the petition's third request is moot, and it is neither necessary nor an efficient use of our resources to address the petitioners' assertions regarding the safety of the food additive use of potassium perchlorate that is no longer authorized. Where helpful for clarity, this notification will describe the petition's arguments regarding the food additive use of potassium perchlorate in the course of reviewing the petition's requests to revoke TOR exemption No. 2005–006 and to issue a new regulation under part 189.

C. The Scope of a Food Additive Petition

The petitioners designated their petition as a ''food additive petition.'' A food additive petition must either propose the issuance of a regulation prescribing the conditions under which a food additive may be safely used (see section 409(b)(1) of the FD&C Act), or propose the amendment or repeal of an existing food additive regulation (see section 409(i) of the FD&C Act).

Only one of the petition's requested actions falls within the statutory scope of a food additive petition: Amending § 177.1210 to remove potassium perchlorate as an allowed additive in sealing gaskets for food containers, the action we are taking in response to the abandonment petition. Because the petition's other two requests—the revocation of TOR exemption No. 2005–006 and the issuance of a regulation under part 189 prohibiting the use of perchlorate in the manufacture of antistatic agents to be used in food-contact articles—are not directed at regulations issued under the food additive petition process, they are governed by different regulations and are not subject to the statutory processes for food additive petitions.

TOR substances, *i.e.,* substances used in food-contact articles that become a component of food at levels that are below the threshold of regulation and meet the criteria in § 170.39, are exempt from regulation as food additives and do not require a listing regulation or food additive petition (see §§ 170.3(e)(2) and 171.8). As noted in the filing notice for this petition, the procedures for reevaluating and revoking a TOR exemption are set forth in § 170.39(g). These procedures are distinct from the food additive petition process. A request to revoke a TOR exemption is the proper subject of a citizen petition submitted under 21 CFR 10.30.

The petition's request that we issue a new regulation under part 189 also falls outside the scope of a food additive petition. A proposed part 189 regulation does not propose the issuance of a new food additive regulation or the amendment or repeal of an existing food additive regulation (see sections 409(b)(1) and (i) of the FD&C Act). Under part 189, an interested person can use the citizen petition process to request a regulation prohibiting a substance from human food (see § 189.1(c) (referring to 21 CFR part 10, which sets forth FDA's citizen petition process)).

Although the requests to revoke the approval of TOR exemption No. 2005–006 and to issue a new regulation under part 189 are outside the scope of a food additive petition, for reasons of administrative efficiency, we initially considered these requests in conjunction with the petition's request to amend § 177.1210 to remove potassium perchlorate as an allowed additive in sealing gaskets for food containers. Because the food additive use of potassium perchlorate has been removed from § 177.1210 in response to the abandonment petition, it is neither necessary nor an efficient use of resources to address the petition's assertions regarding this use of perchlorate. Nonetheless, because we considered all of these requests together for purposes of administrative efficiency, we are addressing the

petition's requests to revoke the approval of TOR exemption No. 2005–006 and to issue a new regulation under part 189 in this document. However, although we are addressing these requests in connection with our denial of a food additive petition, we emphasize that these requests are not the proper subject of a food additive petition. Our denial of these two requests is a final Agency decision, but is not an order under section 409(c)(1)(B) of the FD&C Act.

D. Background on Perchlorate

Perchlorate can interfere with the normal functioning of the thyroid gland by competitively inhibiting the transport of iodide into the thyroid. Iodide is an important component of two thyroid hormones, T4 and T3, and the transfer of iodide from the blood into the thyroid is an essential step in the synthesis of these two hormones. Iodide transport into the thyroid is mediated by a protein molecule known as the sodium (Na^+)-iodide (I^-) symporter (NIS). NIS molecules bind iodide with high affinity, but they also bind other ions that have a similar shape and electric charge, such as perchlorate. The binding of these other ions to the NIS can inhibit iodide transport into the thyroid, which can result in intrathyroidal iodide deficiency and consequently decreased synthesis of T4 and T3 (73 FR 60262, 60266, October 10, 2008). In fetuses, infants, and young children, thyroid hormones are critical for normal growth and development. Id. at 60275. For example, sustained thyroid hormone decrement in a pregnant mother could lead to adverse neurodevelopmental effects in the fetus. Id. at 60266. Research in this area is ongoing.

As part of its discussion asserting that new information is available that raises question as to the safety of the allowed food-contact uses of perchlorates, the petition cited two reviews on perchlorate requested by the Environmental Protection Agency (EPA): A 2005 National Research Council (NRC) review (Ref. 2) and the 2013 report of the EPA's Scientific Advisory Board (SAB) (Ref. 3). The 2005 NRC report noted that thyroid iodide uptake inhibition (IUI) is the only effect that has been consistently documented in humans exposed to perchlorate. Therefore, as part of its review, the NRC utilized a hypothetical mode-of-action (MOA) framework, which represents a continuum of possible biological effects resulting from perchlorate exposure, to describe the potential pathway of events following perchlorate exposure. This MOA framework hypothesized that IUI could induce thyroid hormone changes to an extent that could ultimately result in neurodevelopmental effects in fetuses and infants. The SAB utilized a similar MOA framework. In both MOA frameworks, IUI is the determinant, non-adverse precursor effect, which must occur prior to any later adverse effect.

1. 2005 NRC Review

The 2005 NRC report was prepared in response to a request from the EPA that the National Academy of Sciences review the science regarding potential adverse effects of disruption of thyroid function and provide recommendations to apply this information to a risk assessment for environmental contamination from perchlorate. The report recommended that EPA derive a reference dose (RfD) for perchlorate by applying a tenfold intraspecies uncertainty factor to a no observed effect level (NOEL) based on the initiation of IUI as determined in a human study (Ref. 4). (The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The NOEL is an exposure level at which there are no statistically or biologically significant increases in frequency or severity of any effect between the exposed population and its appropriate control.) The NRC stated that this approach was conservative and protective of health given that the NOEL is based on the non-adverse effect of IUI, which precedes the continuum of possible adverse effects as a result of perchlorate exposure. According to the NRC, the application of the uncertainty factor accounts for differences in sensitivity between the healthy human subjects of the determinant clinical study and ''even the most sensitive populations'' for perchlorate exposure, which the NRC identified as fetuses of pregnant women who may have hypothyroidism or iodide deficiency. (Hypothyroidism is a condition where ''the thyroid gland does not produce enough thyroid hormones to meet the body's needs'' (Ref. 5)). EPA adopted the NRC's recommendations resulting in an RfD of 0.7 micrograms perchlorate/kilogram body weight/day (µg/kg bw/d) (Ref. 6).

2. 2013 EPA SAB Report

The 2013 SAB report was developed in response to a request by EPA for guidance on a suitable approach to utilize relevant available information to derive a maximum contaminant level goal (MCLG) for perchlorate in drinking water. The Safe Drinking Water Act defines an MCLG as the level of a contaminant in drinking water ''at which no known or anticipated adverse effects on the health of persons occur and which allows for an adequate margin of safety.'' 42 U.S.C. 300g–1(b)(4). An MCLG is a nonenforceable public health goal. EPA generally derives an MCLG using the RfD and specific chemical exposure factors. (Ref. 7). Rather than this default approach, the SAB recommended that EPA expand existing physiologically-based pharmacokinetic/pharmacodynamics (PBPK/PD) models to relate perchlorate exposure, in combination with iodide intake, beyond IUI to downstream MOA framework effects, such as resultant thyroid hormone perturbations and potential adverse neurodevelopmental outcomes. The SAB also recommended that the sensitive populations for exposure to perchlorate that EPA should consider when determining an MCLG are the fetuses of hypothyroxinemic pregnant women (hypothyroxinemia means that the free thyroxine (fT4) value is at lower end of the normal range with normal levels of thyroid stimulating hormone (Ref. 8)) and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women.

III. Review of the Petition

The petition asserted that the original request for TOR exemption No. 2005–006 contained errors that should have made the request ineligible for a TOR exemption under § 170.39. The petition also asserted that we made additional errors in exempting the proposed use of sodium perchlorate monohydrate from regulation as a food additive. The petition also identified four categories of ''significant new information that raises questions about the dietary concentration or the safety of a substance that [FDA] has exempted from regulation,'' that it contends warrant reevaluation of TOR exemption No. 2005–006 under § 170.39(g). Lastly, the petition asserted that infants are likely to be disproportionately impacted by perchlorate, and that we have an obligation under Executive Order 13045 (see 62 FR 19885, April 23, 1997) to address risks to infants from perchlorate exposure. The petition also requested that FDA issue a new regulation under part 189 to prohibit the use of perchlorate as a conductivity enhancer in the manufacture of antistatic agents to be ''applied to food contact articles.''

We will first address the petition's arguments regarding the review of TOR exemption No. 2005–006, then address

the petition's arguments based on ''significant new information,'' then subsequently address the assertions pertaining to our obligation under Executive Order 13045, and finally, the request that we issue a new regulation under part 189.

A. Arguments Regarding Review of TOR Exemption No. 2005–006

The petition claimed that multiple errors were made in the original calculation of dietary exposure resulting from the use allowed by the TOR exemption No. 2005–006 and that assumptions used in that calculation were either improperly applied or have been shown to be flawed based on new information available after the TOR exemption became effective. The petition stated further that if these alleged errors were addressed, the dietary exposure resulting from the use allowed by the TOR exemption No. 2005–006 would exceed the TOR exemption criteria.

We describe the background for TOR exemption No. 2005–006 in section III.A.1. The issues raised in the petition concerning alleged errors in the original calculation and assumptions used in that calculation, as well as our responses to those issues, are discussed in sections III.A.2 through III.A.6.

1. Background for TOR Exemption No. 2005–006

Our regulations, at § 170.39(a)(2), provide the exposure criteria for a TOR exemption. As stated in § 170.39(a)(2)(i), the use of a substance will be exempted from regulation as a food additive if the use in question is shown to result in or may be expected to result in dietary concentrations at or below 0.5 parts per billion (ppb), corresponding to dietary exposure levels at or below 1.5 µg of substance/person/day (based on a diet of 1,500 grams (g) of solid food and 1,500 g of liquid food per person per day). As noted in section II.A.2, § 170.39(g) sets forth the procedures for reevaluating and revoking a TOR exemption.

We have issued guidance documents to help interested parties when preparing premarket submissions for food contact substances. Our guidance document specific to chemistry recommendations for food contact substances (Ref. 9) (''chemistry guidance'') provides recommendations for: (1) Migration protocols to determine or estimate the concentration of a food contact substance in the specific food that contacts a given food-contact article containing the substance as a result of the intended use of that substance (''the migration of a substance'') and (2) how to use this information to calculate the resultant total dietary exposure to the substance as a result of its intended use. Our chemistry guidance provides general protocols for food-contact articles intended for single use, as well as general recommendations for articles intended for repeated use.

The chemistry guidance also provides recommended migration protocols for certain specific use applications, including articles intended for use only with non-fatty, dry foods (termed ''Food Type VIII'' in our chemistry guidance). Specific to non-fatty, dry foods, the recommended protocol includes an assumption that a food contact substance migrates into non-fatty, dry foods at a level of 50 µg substance per kilogram food, or 50 ppb. To determine total dietary exposure to a substance as a result of its intended use, the chemistry guidance recommends the application of a consumption factor to the concentration in food determined from the migration protocol. The consumption factor describes the fraction of the daily diet expected to contact a specific type of packaging material. Consumption factors are derived using information on the types of food consumed, the types of food contacting each packaging surface, the number of food packaging units in each food packaging category, the distribution of container sizes, and the ratio of the weight of food packaged to the weight of the package (Ref. 9).

The request for TOR exemption No. 2005–006 was submitted to FDA by Ciba Specialty Chemicals Corporation (Ciba) on June 17, 2005. Although Ciba calculated exposure for sodium perchlorate monohydrate, in this document we convert Ciba's exposure numbers to exposure to the perchlorate anion (the substance of toxicological concern is the perchlorate anion and EPA's RfD for perchlorate is expressed on a perchlorate anion basis). To determine the concentration of perchlorate anion (*i.e.,* ''perchlorate'') in food that contacts finished articles containing sodium perchlorate monohydrate as a result of TOR exemption No. 2005–006, Ciba applied the percentage of sodium perchlorate monohydrate in the finished food-contact article to the 50 ppb migration concentration assumption for non-fatty, dry foods listed in our chemistry guidance. This resulted in a sodium perchlorate monohydrate concentration in food of 0.6 ppb, which corresponds to a concentration of 0.4 ppb for perchlorate in food. To determine a total dietary concentration for perchlorate as a result of this specific use, Ciba then applied our consumption factor for substances that may be used in all polymers but only for specific uses (0.05) to this concentration value. This resulted in a total dietary concentration for sodium perchlorate monohydrate of 0.03 ppb, or 0.02 ppb for perchlorate. For comparison against the TOR exemption exposure criteria stipulated in § 170.39(a)(2)(i), Ciba subsequently multiplied this total dietary concentration by FDA's assumption that an individual consumes 3 kg of food per day. This resulted in a dietary exposure of 0.09 µg sodium perchlorate monohydrate/person/day, or 0.063 µg perchlorate/person/day. A review that we conducted before TOR exemption 2005–006 became effective determined that the provided information demonstrated that the use would result in a dietary exposure below the 1.5 µg/person/day TOR exemption criteria (Ref. 10).

2. Issues Pertaining to Calculations Based on FDA's Chemistry Guidance

The petition asserted that Ciba deviated from the recommendations provided in FDA's chemistry guidance when calculating the exposure to perchlorate that results from the intended use for the TOR exemption No. 2005–006. Specifically, the petition asserted that applying the percentage of sodium perchlorate monohydrate in the finished food-contact article to the 50 ppb migration concentration assumption deviates from the recommended migration protocol for non-fatty, dry foods and improperly made Ciba's intended use for sodium perchlorate monohydrate eligible for a TOR exemption. Furthermore, the petition said that the original TOR exemption submission did not account for the recommendations presented in FDA's chemistry guidance for substances in food-contact articles intended for repeated-use.

a. *Applying the percentage of sodium perchlorate in the finished food-contact article to the 50 ppb migration concentration assumption.* The petition asserted that Ciba ''varied'' from our chemistry guidance when it ''inserted the amount of perchlorate in the formulation (4%) and the amount of formulation in the packaging (30%) into'' the equation for calculating the dietary concentration of sodium perchlorate monohydrate. Specifically, Ciba applied the percentage of sodium perchlorate monohydrate in the finished food-contact article (4% × 30% = 1.2%) to the 50 ppb migration concentration assumption.

We acknowledge that our chemistry guidance does not specifically discuss a procedure for applying the percentage of

a substance in the finished food-contact article to the 50 ppb migration concentration assumption for the food contact substance, but applying such a percentage to a migration concentration assumption does not deviate from that guidance. The migration protocol for Food Type VIII is written at a general level and does not preclude scientifically appropriate calculations based on the percentage of a food contact substance when using the 50 ppb migration concentration assumption. We believe it was scientifically appropriate for Ciba to apply the percentage of the food contact substance in the finished packaging to the 50 ppb migration concentration assumption. Ciba's calculation noted that sodium perchlorate monohydrate represents only a small fraction of the antistatic agent in which it is used (4 percent), and the antistatic agent itself represents only a fraction of the finished food-contact article in which it is used (30 percent). Therefore, absent contradictory data, it is scientifically reasonable to assume that sodium perchlorate monohydrate migrates to Food Type VIII at the level that it is present in the finished food-contact article (*i.e.,* 1.2 percent of the 50 ppb migration concentration assumption). Such percentages have been applied to migration concentration assumptions in other submissions that have been approved or become effective (Ref. 11).

We also note that the chemistry guidance states that dry foods with the surface containing no free fat or oil typically exhibit little or no migration, and cites volatile or low molecular weight adjuvants as examples of substances that would be expected to migrate into non-fatty, dry foods. Sodium perchlorate monohydrate is an ionic compound with low volatility and therefore would not be expected to migrate from food-contact materials into non-fatty, dry foods (Ref. 11). Therefore, there is no scientific basis to suggest that sodium perchlorate monohydrate would migrate into non-fatty, dry foods at a higher percentage of the 50 ppb migration concentration assumption than its percentage in the food-contact article.

The appropriateness of Ciba's approach of applying the percentage of sodium perchlorate monohydrate in the finished food-contact article to the 50 ppb migration concentration assumption is supported by available analytical data provided in comments to the docket for the petition. The migration protocol specific to non-fatty, dry foods provided in our chemistry guidance recommends either the estimation of the migration of a substance using the 50 ppb migration concentration assumption or the determination of the actual migration via appropriate migration studies. Comments submitted to the docket for the petition include a migration study for sodium perchlorate monohydrate from a worst-case polymeric resin into a simulant for non-fatty, dry foods (see Docket Nos. FDA–2015–F–0537, Supplemental Comments from BASF Corporation (Keller and Heckman LLP) (FDA–2015–F–0537–18), BASF Corp Migration Report (Redacted) re: Supplemental Comments from BASF Corporation (Keller and Heckman LLP) (FDA–2015–F–0537–19), BASF Corporation Appendix A—Analysis Method (Redacted) re: Supplemental Comments from BASF Corporation (Keller and Heckman LLP) (FDA–2015–F–0537–20), BASF Corporation Appendix B—Detailed Sample Analysis Data (Redacted) re: Supplemental Comments from BASF Corporation (Keller and Heckman LLP) (FDA–2015–F–0537–21), BASF Corporation Appendix C—Chromatograms (Redacted) re: Supplemental Comments from BASF Corporation (Keller and Heckman LLP) (FDA–2015–F–0537–22), and BASF Corporation Appendix D—Spiking Validation at Low Perchlorate (Redacted) re: Supplemental Comments from BASF Corporation (Keller and Heckman LLP) (FDA–2015–F–0537–23)). We reviewed this study and determined that it is adequate to determine worst-case migration of perchlorate into non-fatty, dry foods as a result of the use specified in the TOR exemption No. 2005–006 (Ref. 11). As such, the migration concentration in food for perchlorate as determined from this migration study can be used to verify the appropriateness of Ciba's approach of applying the percentage of sodium perchlorate monohydrate in the finished food-contact article to the 50 ppb migration concentration assumption.

The migration study reported its results on a basis of grams of perchlorate per surface area of test sample. To convert this reporting basis to grams of perchlorate per gram of food, we applied our standard assumption for the food mass-to-surface area ratio for consumer packaging (10 g of food contacting each square inch of food-contact article) to the results of the migration study. This results in a migration concentration of 0.5 nanogram (ng) perchlorate/g food, or 0.5 ppb. This value is substantially less than the 50 ppb migration concentration assumption provided in our chemistry guidance and is essentially equivalent to the 0.4 ppb concentration for perchlorate in food calculated using Ciba's approach in its TOR submission. The dietary exposure to perchlorate calculated using the concentration for perchlorate in food obtained from the migration study (0.075 µg/person/day) is also essentially equivalent to that calculated using Ciba's approach (0.063 µg/person/day) and is lower than the TOR exemption criteria of 1.5 µg/person/day. The results of the migration study confirm that Ciba's approach to calculating migration was scientifically appropriate. Both the migration study and Ciba's approach resulted in dietary exposure figures for sodium perchlorate monohydrate that were lower than the TOR exemption criteria. Therefore, the petition's assertion that the intended use of sodium perchlorate monohydrate would not be eligible for a threshold of regulation exemption if migration had been properly calculated is unfounded.

b. *Calculation of dietary exposure based on migration protocol.* As discussed in section III.A.1, FDA's chemistry guidance discusses general protocols for food-contact articles intended for single-use (*e.g.,* a disposable paper cup), as well as for articles intended for repeated-use (*e.g.,* a reusable ceramic mug). Part I.C.5 of the petition noted that Ciba's calculation of dietary exposure ''did not rely'' on the recommended migration protocol in our chemistry guidance for food-contact articles intended for repeated use. Related to this argument, in the December 5, 2014, submission, the petitioners asserted that Ciba's use of a single-use protocol, rather than a repeated-use protocol, does not account for the release of perchlorate over time ''as the plastic degrades or is flexed.''

Using the single-use protocol results in a higher exposure value than using the repeated-use protocol because: (1) The factors applied to the migration value to determine exposure in the single-use protocol are exaggerative and (2) exposure values from repeated-use articles are typically very small in comparison to single-use articles. Therefore, when a food contact substance will be used in both single- and repeated-use articles, it is more conservative and protective to use the single-use protocol to determine exposure than it is to use the repeated-use protocol. Accordingly, where, as here, a food contact substance is intended to be used in both single- and repeated-use food-contact articles, we use the single-use protocol to determine exposure. We only use the repeated-use protocol for food contact substances that are only used in repeated-use food-contact articles. As Ciba's intended use

of sodium perchlorate monohydrate was not limited to repeated-use food-contact articles, its use of the single-use protocol, rather than the repeated-use protocol, was appropriate.

i. *Background on migration protocols.* The migration protocols in the chemistry guidance provide recommendations on: (1) How to determine the total migration of a substance from a given food-contact surface area (migration value) and (2) how to use that migration value to determine dietary exposure to the migrating substance based upon the mass of food the food-contact surface area will come into contact with and the percentage of the diet that mass of food constitutes. The single-use and repeated-use protocols both provide similar recommendations on how to determine the total amount of migration of a substance from a given food-contact surface area; however, they differ in the assumptions used to determine dietary exposure from that migration value. Specifically, to determine dietary exposure, the single-use protocol applies the following factors to the migration value: (1) FDA's standard assumption of the amount of food in contact with a given surface area of a single-use articles (10 g of food contacting each square inch of food-contact article); (2) food-type distribution factors to account for the variable nature of the food contacting each food-contact article (when applicable); and (3) consumption factors (*i.e.,* the fraction of the daily diet expected to contact a specific type of packaging material). Ciba's calculation did not use food-type distribution factors, and we will not discuss such factors further. By comparison, the repeated-use protocol recommends that dietary exposure be determined by applying to the migration value an estimate of the total mass of food contacting a known food-contact surface area over the service life of the article.

ii. *Use of the single-use protocol for substances in both single- and repeated-use articles.* We consider the exposure calculated from the single-use protocol to address the exposure to a food contact substance used in both single- and repeated-use articles for several reasons, including that: (1) The factors applied to the migration value to determine exposure in the single-use protocol are exaggerative and (2) exposure values from repeated-use articles are typically very small in comparison to single-use articles.

We consider the factors applied to the migration value to determine exposure in the single-use protocol to be exaggerative for several reasons. For instance, the use of a consumption factor in the single-use protocol assumes that the food contact substance will be used in all food-contact articles that utilize the specific type of material to which the consumption factor applies (as discussed in section III.A.1, consumption factors are specific to a material—*e.g.*, glass, paper, or plastic—in that the consumption factor describes the fraction of the daily diet expected to contact packaging that utilizes that type of material). This is an exaggerative assumption. Food contact substances are used in food-contact articles to perform a specific technological function. It is highly unlikely that all food-contact articles that use the type of packaging material to which a specific consumption factor applies will require that technological function. In addition, the use of a consumption factor does not account for the use of alternative food contact substances that perform the same technological function. The following example illustrates the exaggerative nature of the use of a consumption factor: Under the single-use protocol one could use FDA's consumption factor for colored plastics to determine exposure to a black pigment intended to be added to plastic food packaging. FDA's consumption factor for colored plastics describes the fraction of the daily diet expected to contact packaging that consists of colored plastic, regardless of the color of that plastic. However, not all colored plastic is black, and, therefore, a black pigment would not be added to all colored plastics. In addition, there are multiple black pigments that are authorized to color food-contact articles. Given that alternative black pigments are available for the same purpose, it is unlikely that all black colored plastic packaging would use the particular black pigment at issue.

We also note that exposure values from repeated-use articles are typically very small in comparison to single-use articles because individual repeated-use articles come into contact with significantly larger amounts of food over their service lifetime than individual single-use articles. This results in a much greater food mass-to-surface area ratio for repeated-use articles than the 10 g of food contacting each square inch of food-contact article assumption for single-use articles. The greater food mass-to-surface area ratio for repeated-use articles means that the total amount of migration of a substance from a given food-contact surface area (the migration value) is diluted across a much larger amount of food in comparison to a single-use article, resulting in a significantly lower dietary concentration.

In conclusion, we consider the exposure to a food contact substance used in both single- and repeated-use articles to be addressed by the exaggerative exposure calculated via the single-use protocol. Therefore, we apply the single-use protocol to food contact substances intended to be used in both single-use and repeated-use food-contact articles.

iii. *Applying worst-case assumptions to available migration information.* In any event, we note that the migration study described in section III.A.2.a followed equivalent or more stringent specifications than those recommended in the single- and repeated-use protocols. In section III.A.3, we explain that, even if the absolute worst-case assumptions for both the single- and repeated-use protocols discussed in the chemistry guidance—that each square inch of food-contact article will come into contact with 10 g of food, and that the article will come into contact with all food in a consumer's diet (in other words, no consumption factors or food type distribution factors are applied to the migration value)—are applied to the migration value determined from this study, the calculated dietary exposure to perchlorate would still fall within the TOR exposure exemption criteria. As such, the petitioners' assertions that Ciba did not follow the repeated-use protocol discussed in the chemistry guidance document and that use of a single-use protocol did not account for the release (*i.e.,* migration) of perchlorate over time if the finished article degrades or is flexed, do not support the conclusion that TOR exemption No. 2005–006 should be revoked.

3. Issues Pertaining to the Use of a Consumption Factor When Calculating Dietary Exposure

The original calculation of dietary exposure resulting from the use allowed by the TOR exemption No. 2005–006 used FDA's consumption factor for substances that may be used in all polymers but only for specific uses. The petition asserted that the use of a consumption factor in this instance is inappropriate for a variety of reasons, including that the consumption factor does not account for the use of sodium perchlorate monohydrate in all antistatic agents and all polymers, nor in reusable bulk packaging for raw materials which the petition said result in finished articles containing sodium perchlorate monohydrate coming into contact with food ingredients that will later be used in the production of

processed foods which are not limited to non-fatty, dry foods.

To address the petition's assertions regarding the appropriateness of the use of a consumption factor, we used the results of the migration study provided in comments submitted to the docket for the petition (discussed in section III.A.2.a) to calculate the dietary exposure to perchlorate from the use allowed by TOR exemption No. 2005–006 without the use of a consumption factor (Ref. 11). This approach overestimates the dietary exposure from the use allowed by TOR exemption No. 2005–006 because it assumes that finished articles containing sodium perchlorate monohydrate will come into contact with all foods in a consumer's diet instead of coming into contact with just non-fatty, dry foods. This approach also assumes that all food will come into contact with articles containing sodium perchlorate monohydrate at the maximum allowed use level, which is a conservative assumption because it can be expected that not all finished articles would utilize the substance at the maximum allowed use level. In addition, this calculation utilizes our food mass-to-surface area ratio assumption for consumer (single use) packaging, even though it can be expected that food-contact articles used in food processing and raw material storage have a much larger food mass-to-surface area ratio than consumer packaging (see discussion in section III.A.2.b.ii).

Using this conservative approach, we calculated a perchlorate exposure of 1.5 µg/person/day, which falls within the TOR exemption criteria specified in § 170.39(a)(2)(i) even without the use of a consumption factor. This calculation demonstrates that the assertions raised in the petition pertaining to the use of a consumption factor do not support a conclusion that TOR exemption No. 2005–006 is no longer supportable under § 170.39(g).

4. Inclusion of Use in Contact With Infant Formula and Food for Children Younger Than Two Years Old

As discussed in section III.A.1, the original submission for TOR exemption No. 2005–006 calculated the dietary exposure to perchlorate from the intended use of sodium perchlorate monohydrate. This calculation used several factors, including a consumption factor as well as an assumption of a total food consumption of 3 kg of food per day. Section I.C.3 of the petition stated that because these factors are specific to adults, exposure calculated using these factors could underestimate perchlorate exposure for infants relying on powdered formula as their sole source of nutrition if sodium perchlorate monohydrate was used in infant formula packaging as a result of TOR exemption No. 2005–006. The petition stated that many infants rely on infant formula as their sole source of nutrition, whereas adults consume a diverse diet. The petition also stated that infants consume more food per bodyweight than adults.

a. *Section 170.39(a)(2)(i) and the use of specific factors to calculate exposure.* As discussed in section III.A.1, § 170.39(a)(2)(i) requires that dietary exposure be calculated using a specified assumption of 3 kg of food per day, which is an assumption for the general adult population. In addition, § 170.39(a)(2)(i) requires that dietary exposure be expressed on a per person basis (µg/person/day), which does not account for the fact that infants consume more food per bodyweight than adults. To account for the fact that infants consume more food per bodyweight than adults, infant dietary exposure would need to be expressed on a bodyweight basis (µg/kg bodyweight/day). Section 170.39(a)(2)(i) does not preclude the use of a consumption factor when calculating exposure; as discussed in section III.A.3, the use of a consumption factor refines exposure by taking into account the fraction of the daily diet expected to contact a specific type of packaging material rather than assuming a given food contact substance will be used in contact with all food in a consumer's diet. However, in section III.A.3 we also demonstrate that the dietary exposure to perchlorate that results from the intended use subject to TOR exemption 2005–006 falls within the TOR exemption criteria even if that exposure is calculated without the use of a consumption factor.

b. *Section 170.39(b) and infant exposure to perchlorate from the TOR use.* Although the intended use for TOR exemption No. 2005–006 results in an exposure of 1.5 µg/person/day or less using the assumptions specified in § 170.39(a)(2)(i), under § 170.39(b) we can decline to grant a TOR exemption in those cases where the available information establishes that the proposed use may pose a public health risk. In certain circumstances, we believe that infants' dietary exposure to a substance may be relevant to whether the proposed use of a substance may pose a public health risk under § 170.39(b). Therefore, to address the petition's argument that the use of adult-specific exposure assumptions could underestimate perchlorate exposure for infants that solely consume reconstituted powdered formula, we calculated a potential exposure to perchlorate in powdered formula from the intended use allowed by TOR exemption No. 2005–006. We calculated this potential infant dietary exposure by applying infant-specific exposure assumptions articulated in FDA's draft guidance for food contact notification submissions for food contact substances that contact infant formula or human milk (Ref. 12), to data from the migration study provided in comments submitted to the docket for the petition (discussed in Section III.A.2.). These infant-specific dietary exposure assumptions include an assumption that an infant (aged 0 to 6 months) consumes 900 g of liquid formula per day (data from the National Health and Nutrition Examination Survey indicate that the highest mean intake for infants 0–6-months is for 2-month old infants, which have an intake of 900 grams/day). FDA also used the corresponding mean body weight of 2-month olds of 6.3 kg bodyweight/infant. The infant-specific potential dietary exposure estimate excludes the use of a consumption factor, because infants aged 0 to 6 months frequently consume human milk and/or infant formula exclusively. Using this approach, we calculated a potential infant dietary exposure to perchlorate in powdered formula from the intended use allowed by TOR exemption No. 2005–006 of 0.019 µg/kg bodyweight/day (Ref. 11). As discussed in section III.B, the petition discusses the safety of perchlorate exposure in the context of the RfD for perchlorate, as well as a value derived from a preliminary, biologically based dose-response model. This calculated potential perchlorate exposure for powdered formula is less than both the RfD for perchlorate (0.7 µg/kg bodyweight/day) and the value derived from the model (0.42 µg/kg bodyweight/day). Thus, the petition does not demonstrate that there is a public health risk to infants under § 170.39(b) as a result of the intended use of perchlorate allowed by TOR exemption No. 2005–006.

5. Consideration of Exposure From Other Sources

The petition asserted that section 409(c)(5)(B) of the FD&C Act and § 170.3(i)(2) require consideration of cumulative exposure to perchlorate in the review of TOR exemption No. 2005–006 and that, if these exposures are considered when calculating the dietary exposure for the TOR exemption, the resultant exposure may exceed the TOR exemption criteria of dietary exposure at or below 1.5 µg/person/day. Specifically, the petition stated that the

original calculation of dietary exposure resulting from the use allowed by TOR exemption No. 2005–006 did not consider dietary exposure to perchlorate as a result of the approved food-contact use of potassium perchlorate listed in § 177.1210, nor as a result of environmental contamination of the food supply.

The use of a food contact substance that is exempted from regulation as a food additive under FDA's TOR regulation is not subject to the factors that apply to the proposed use of a food additive under section 409(c)(5)(B) of the FD&C Act and § 170.3(i)(2). Rather, when we exempt a food-contact use of a substance from regulation as a food additive, our TOR regulation ensures the safety of this food-contact use by setting extremely low limits on migration levels so that its proposed use results in a negligible dietary concentration, and requiring that the substance not be a carcinogen. A premise of the TOR regulation is that if a substance meets these requirements, it presents no other health or safety concerns (see § 170.39(a)(2)). In determining whether the use of a substance qualifies for a TOR exemption, cumulative exposure to a substance is not considered under the TOR regulation because the dietary exposure from the use of a substance that is at or below the threshold of regulation is negligible. Thus, § 170.39(a)(2)(i) provides that the only dietary exposure that is relevant to whether the use of a substance qualifies for a TOR exemption from regulation as a food additive is the dietary exposure resulting from the use in question.

We established the threshold of regulation set forth in § 170.39(a)(2)(i) based on available toxicological data showing that it was feasible to establish a threshold level below which dietary exposures to substances used in food-contact articles are so negligible as to pose no public health or safety concerns (see 60 FR 36582, July 17, 1995). In the preamble to the proposed TOR rule, we explained that our analysis of toxicological data on a large number of representative compounds demonstrated that the noncarcinogenic toxic effects caused by the majority of unstudied compounds would be unlikely to occur below 1,000 ppb (58 FR 52719 at 52722, October 12, 1993). To provide an adequate safety margin, we selected 0.5 ppb as the threshold for regulation, which is 2,000 times lower than the dietary concentration at which the vast majority of studied compounds are likely to cause noncarcinogenic toxic effects (see 58 FR 52719 at 52722). We also analyzed potency data on a large number of known carcinogens to determine that the 0.5 ppb dietary concentration level would result in negligible risk, even in the event that a substance that is exempted from regulation as a food additive were later shown to be a carcinogen (see 58 FR 52719 at 52722).

Consistent with § 170.39(a)(2)(i), we do not calculate cumulative exposure to a substance in evaluating whether the use of the substance qualified for a TOR exemption. As we explained in an April 2002 guidance for industry entitled, ''Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations,'' at the time the TOR process was established, FDA determined that, because of the conservative assumptions ordinarily applied in estimating exposure, the cumulative exposure from a limited number of trivial food additive uses is not likely to be more than negligible. Accordingly, in the case of the TOR exposure levels, it was not necessary to utilize cumulative exposure levels. FDA believes that the determination made in establishing its TOR is still sound (Ref. 13).

Therefore, contrary to the petition's assertions, under FDA's TOR regulations, the dietary exposures to perchlorate that are not a result of the use specified in the TOR exemption No. 2005–006 are not considered under the exposure criteria for the TOR exemption.

6. Inconsistencies Between the Intended Use Reviewed by FDA and That Listed on Our Inventory of Effective TOR Exemptions

We maintain an inventory of effective TOR exemptions on our Web site (Ref. 1). The originating submission for TOR exemption No. 2005–006 requested a use for sodium perchlorate monohydrate in antistatic agents at a maximum level of 4 percent by weight. The antistatic agent would be used in finished plastic at a maximum level of 30 percent by weight. The finished plastic would be used in contact with non-fatty, dry foods (Food Type VIII) only. This is the intended use that we considered in 2005 when we determined that the information provided in the originating request demonstrated that the use would result in a dietary exposure at or below the 1.5 µg/person/day criteria. The petition asserted that this intended use was expanded in the final letter for the TOR exemption No. 2005–006 to permit the finished article to be used in contact with all dry foods. The petition also asserted that the intended use was further expanded in the listing on our inventory of effective TOR exemptions, to include the use of sodium perchlorate monohydrate in all types of food contact materials at a maximum use level of 4 percent by weight in the finished article.

We agree that the intended use for TOR exemption No. 2005–006 was inaccurately described in the final letter for the TOR exemption No. 2005–006 and the inventory of effective TOR exemptions. On August 17, 2015, we corrected the listing for TOR exemption No. 2005–006 on the inventory of effective TORs on our Web site to be consistent with the intended use reviewed by FDA when the TOR exemption became effective and thereby address the petition's assertions regarding the description of the intended use for TOR exemption No. 2005–006. We further revised the listing for TOR exemption No. 2005–006 on September 19, 2016, to clarify that TOR exemption No. 2005–006 allows the use of perchlorate in the manufacture of antistatic agents for use in all polymeric food-contact articles and not only polymeric food packaging.

B. Arguments Based on ''Significant New Information''

Part I.D. of the petition identified the following four categories of ''significant new information'' that has become available after TOR exemption No. 2005–006 became effective: ''First, additional research shows that the endpoint used in the decision was not the most appropriate or sensitive one to protect fetuses and infants from permanent brain damage. Second, it is now known that nitrates and thiocyanates are pharmacologically-related to perchlorate and, therefore, must be considered in any safety evaluation of perchlorate as an additive. Third, in 2011, FDA acknowledged that the 50 ppb migration to dry-food default assumption (''virtually nil'' migration) may be flawed based on research evidence from Europe. Fourth, FDA has demonstrated that there is widespread contamination of the food supply with perchlorate that must be considered.'' The petition asserted that this new information warrants a reevaluation of TOR exemption No. 2005–006 under § 170.39(g).

We will first address the petition's arguments regarding hypothyroxinemia and its proposed acceptable daily intake level, then discuss the petition's arguments pertaining to perchlorate in the food supply and pharmacologically related substances, and finally the arguments pertaining to our 50 ppb migration concentration assumption.

1. Proposed Acceptable Daily Intake Level Based on Hypothyroxinemia

The petition proposed an acceptable daily intake (ADI) value in place of the RfD for perchlorate and argues that the exposure from the TOR use exceeds the ADI proposed in the petition. The petition stated that the ADI proposed in the petition better accounts for hypothyroxinemia as a potential result of perchlorate exposure than does the RfD. However, under our TOR regulations, because a substance is expected to migrate into food at negligible levels, a non-carcinogenic endpoint such as hypothyroxinemia is not relevant unless the use of the substance may pose a public health risk under § 170.39(b). As discussed further in this section, the information in the petition does not support such a conclusion under § 170.39(b) because: (1) Even if hypothyroxinemia were relevant, the petition does not demonstrate that the proposed ADI better accounts for the potential for perchlorate to cause hypothyroxinemia than the RfD for perchlorate; (2) the proposed ADI is based on the results of a preliminary model; and (3) even if it were appropriate to base an ADI on the results of the preliminary model, the resulting ADI would still be above the exposure from the TOR use.

a. Summary of petition's discussion on hypothyroxinemia. The petition asserted that new information, available since TOR exemption No. 2005–006 became effective, demonstrates that exposure to perchlorate can result in hypothyroxinemia. As noted in section I.D.2, hypothyroxinemia means that the fT4 value is at the lower end of the normal range with normal levels of TSH in the blood. The petition asserted that the SAB report, which was issued after the TOR exemption became effective, identified the potentially sensitive population for perchlorate exposure to be fetuses of hypothyroxinemic pregnant women. This is in contrast to the NRC report, which identified the potentially sensitive population for perchlorate exposure to be fetuses of pregnant women with hypothyroidism or iodide deficiency (both the SAB report and the NRC report are discussed in section I.D.2). Based upon this difference, the petition asserted that the RfD, which was based on the NRC review, does not provide sufficient protection to susceptible populations. The petition also asserted that IUI, which is the basis of the RfD, is a less sensitive endpoint than hypothyroxinemia.

The petition proposed an ADI of 0.042 µg/kilogram bodyweight/day for perchlorate based on the amount of perchlorate exposure that may result in hypothyroxinemia in iodide-deficient pregnant women as reported by FDA scientists in a 2013 Lumen et al. article (Ref. 14). Lumen et al. summarizes the results of a proof-of concept, biologically based dose-response (BBDR, also known as a PBPK/PD) model that is specific to near-term human mothers and fetuses. This model used PBPK/PD data to predict perchlorate intake levels that could produce thyroid hormone perturbations at varying levels of maternal iodide intake. The petition derived its proposed ADI by applying two ten-fold uncertainty factors to the results presented in the Lumen et al. article. One ten-fold uncertainty factor is applied to account for intraspecies variability, while the second tenfold uncertainty factor is applied to account for the assertion that the perchlorate exposure value provided in the Lumen et al. article is based on a lowest observed adverse effect level (LOAEL) rather than a no observed adverse effect level (NOAEL). (The petition also stated that additional, unquantified uncertainty factors should be applied to its proposed ADI to account for deficiencies in the model, but it does not include these factors in its calculation of the proposed ADI.) The petition subsequently compared its proposed ADI to a dietary exposure to perchlorate resulting from the use allowed by TOR exemption No. 2005–006 as calculated in the petition. As the exposure to perchlorate calculated in the petition is higher than the derived ADI, the petition asserted that TOR exemption No. 2005–006 should be revoked.

b. *FDA's consideration of the petition's discussion on hypothyroxinemia.* First, the petition contended that its proposed ADI accounts for the potential for perchlorate to cause hypothyroxinemia while the RfD for perchlorate does not. However, the petition does not adequately support its assertion that the RfD for perchlorate fails to account for the potential for perchlorate to cause hypothyroxinemia (Ref. 15). The SAB's and NRC's identification of different sensitive populations for perchlorate exposure is not a basis for concluding that the RfD provides insufficient protection to the sensitive population identified by the SAB, nor that the RfD does not account for the potential for perchlorate to cause hypothyroxinemia. The RfD for perchlorate is based on the IUI. As previously stated, the basis of the MOA framework for perchlorate is that IUI must first occur prior to any resultant thyroid hormone perturbations such as hypothyroxinemia or hypothyroidism. This contradicts the petition's assertion that IUI is a less sensitive endpoint than hypothyroxinemia. The NRC and SAB used the MOA framework for perchlorate in determining their recommendations. The MOA framework was also used in the development of the Lumen et al. BBDR model cited by the petitioners (Ref. 14). Furthermore, the tenfold intraspecies uncertainty factor utilized by the NRC in the derivation of the RfD is a default value that is intended to account for the entire range of sensitivity among humans to perchlorate exposure. The petition did not provide support for its contention that this default, intraspecies uncertainty factor is not inclusive of fetuses of pregnant women with hypothyroxinemia.

Second, the 2013 Lumen et al. BBDR model that forms the basis of the ADI proposed by the petitioners is a preliminary model (Ref. 15) that FDA believes is not appropriate to use in a quantitative risk assessment as presented in the petition. Because FDA does not believe that the model should be used for a quantitative risk assessment due to the preliminary nature of the analysis, consideration of the appropriateness of the uncertainty factors proposed by the petitioners is premature at this time. Since the 2013 Lumen et al. article, we have worked with EPA scientists to further develop the model cited by the petitioners. On January 10 and 11, 2017, EPA's contractor conducted an independent, scientific public peer review of EPA's draft BBDR model and report. EPA is currently considering peer reviewer comments. EPA intends to seek peer review of a second report that evaluates methods to apply the final BBDR model to develop a maximum contaminant level goal for perchlorate in drinking water (see 81 FR 87553, December 5, 2016).

Third, we note that even if the approach taken in the petition were appropriate—*i.e.,* to calculate a risk assessment value based on the results of the preliminary model referenced in the petition, and to apply both 10-fold uncertainty factors specified in the petition (one to account for a LOAEL and one to account for intraspecies variability) to the amount of perchlorate exposure that may result in hypothyroxinemia in iodide-deficient pregnant women as reported in the Lumen et al. article—the resultant ADI calculated in the petition is 0.042 µg/kg bodyweight/day. This risk assessment value is higher than the exposure to

perchlorate as a result of TOR exemption No. 2005–006 as determined by Ciba (0.063 µg per chlorate/person/day, which equates to 0.001 µg/kg bodyweight/day utilizing FDA's assumption of 60 kg bodyweight for adults as described in the chemistry guidance), as well as the exposures determined from the migration study discussed in section II.A.2 (for adults: 0.075 µg/person/day which equates to 0.001 µg/kg bodyweight/day; and for infants: 0.019 µg/kilogram bodyweight/day—see section II.A.4). Therefore, even if deriving a risk assessment value based on the results presented in the Lumen et al. article were appropriate, the exposure to perchlorate as a result of TOR exemption No. 2005–006 is lower than the resulting risk assessment value, and therefore would not support the assertion by the petitioners that the results presented in the Lumen et al. article ''raises questions about the safe level of exposure to perchlorate relied on by Ciba when the Agency approved TOR No. 2005–006.''

2. Argument Related to Cumulative Dietary Exposure From Perchlorate, and Substances Pharmacologically Related to Perchlorate, in the Food Supply

The petition asserted that new information has become available, since FDA issued the listing regulation for potassium perchlorate in § 177.1210 and TOR exemption No. 2005–006, that nitrate and thiocyanate are pharmacologically related to perchlorate, and that perchlorate contamination of the food supply is widespread. The petition also asserted that we are required to take into account the cumulative effect of these substances in the diet.

As discussed in section III.A.5, under § 170.39(a)(2)(i), we do not calculate cumulative dietary exposure to a substance or pharmacologically related substances in evaluating whether the use of the substance qualifies for a TOR exemption from regulation as a food additive. Under § 170.39(a)(2)(i), the only dietary exposure that is relevant to whether the use of a substance qualifies for a TOR exemption from regulation as a food additive is the dietary exposure resulting from the use in question. Therefore, the petition's argument regarding cumulative dietary exposure to perchlorate or pharmacologically related substances does not support a conclusion that TOR exemption No. 2005–006 is no longer supportable.

3. Alleged Flaws in FDA's 50 ppb Migration Concentration Assumption

The petition stated that FDA, in a 2011 speech by an FDA scientist, acknowledged potential flaws in the 50 ppb migration concentration assumption for migration to non-fatty, dry foods (Food Type VIII). To support this statement, the petition cited a 2011 article which summarizes the speech given by the FDA scientist (Ref. 16). The petition also asserted that the 50 ppb migration assumption is particularly flawed for perchlorate, which is used in packaging to neutralize the static charge on dry food.

The migration study provided in comments submitted to the docket for the petition (discussed in section III.A.2.a) found that perchlorate migrated into a simulant for non-fatty, dry foods at a concentration of 0.5 ng perchlorate/g food, or 0.5 ppb. As noted, this value is substantially less than the 50 ppb migration concentration assumption provided in our chemistry guidance and indicates that the 50 ppb migration concentration assumption does not understate migration from the intended use of sodium perchlorate monohydrate into non-fatty, dry foods. As a result, the petition's contentions regarding alleged flaws in the 50 ppb migration concentration assumption, both generally and as applied to perchlorate, do not support a conclusion that TOR exemption No. 2005–006 is no longer supportable.

C. Alleged Disproportionate Impact of Perchlorate on Children's Health and FDA's Obligation Under Executive Order 13045

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (see 62 FR 19885, April 23, 1997), provides in part that, ''to the extent permitted by law and appropriate, and consistent with the agency's mission,'' each Federal Agency ''shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks,'' which are defined as ''risks to health or to safety that are attributable to products or substances that the child is likely to come in contact with or ingest (such as the air we breath [sic], the food we eat, the water we drink or use for recreation, the soil we live on, and the products we use or are exposed to).'' The petition asserted that, because perchlorate has a disproportionate impact on infants, the Executive Order warrants the use by FDA of additional safety factors beyond those provided in § 170.22 (21 CFR 170.22) when considering the safety of the food-contact uses of perchlorate. Specifically, the petition contended that safety factors in addition to the 100-fold safety factor stated in § 170.22 are necessary due to deficiencies in the Lumen et al. BBDR model (discussed in section III.B.1) and because a pregnant woman's short-term exposure to perchlorate can cause irreversible harm to the fetal brain if the woman has low iodine intake.

We note that § 170.22 pertains to safety factors used in applying animal experimentation data to man. As the safety arguments presented in the petition utilize data obtained from human subjects, and the petition discusses specific safety factors for each argument, § 170.22 is not relevant to the safety arguments presented in the petition. Furthermore, in the December 5, 2014, submission the petition stated that the tenfold safety factor utilized to derive the RfD for perchlorate is consistent with Executive Order 13045.

With respect to the petition's request to apply additional safety factors, section III.B.1 explains that FDA believes the results of the BBDR model are preliminary in nature and not an appropriate basis for a quantitative risk assessment as presented in the petition. A discussion of whether or not uncertainty factors should be applied is premature at this time. For these reasons, we believe that our analysis of the potential health effects of perchlorate satisfies Executive Order 13045 and that the use of additional safety factors is not necessary.

D. Request To Issue a New Regulation Under 21 CFR Part 189

Part II of the petition asserted that, if FDA were to revoke TOR exemption No. 2005–006, publication of the notice of revocation in the **Federal Register** would be insufficient to alert industry, and therefore requested that we issue a new regulation under part 189. The requested regulation would prohibit the use of perchlorates in the manufacture of antistatic agents to be used in food-contact articles, which is the use of perchlorate allowed by TOR exemption No. 2005–006.

Because we conclude that TOR exemption No. 2005–006 remains supportable under § 170.39, we decline to propose a regulation under part 189 prohibiting this use of perchlorate.

IV. Comments on the Filing Notice

We received very few comments on the petition. Those comments that discussed the safety of the use of perchlorate in food contact applications did not provide any additional data to that presented in the petition.

In this section we discuss the issues raised in the remaining comments. We preface each comment discussion with a numbered ''Comment'' and each

response by the word ''Response'' to make it easier to identify comments and our responses. We have numbered each comment to help distinguish among different topics. The number assigned is for organizational purposes only and does not signify the comment's value, importance, or the order in which it was received.

(Comment 1) One comment provided a migration study for sodium perchlorate monohydrate from a worst-case polymeric resin into a dry food simulant.

(Response) This study is discussed in section III.A.2.

(Comment 2) Several comments stated that the use of potassium perchlorate as an additive in closure-sealing gaskets for food containers has been abandoned.

(Response) The abandonment of potassium perchlorate as an additive in closure-sealing gaskets is the subject of a separate food additive petition, 6B4816, which we address elsewhere in this edition of the **Federal Register**.

(Comment 3) Another comment stated that the petition's request that FDA add perchlorate to the list of prohibited substances contained in part 189 is based upon the identification of a hazard relating to a class of chemical substances. The comment asserted that an approach to safety assessment based on hazard identification is a departure from FDA's practice of evaluating the safety of food contact materials based on their intended use.

(Response) As we are declining to propose a regulation under part 189 prohibiting the use of perchlorates as a food contact substance in antistatic agents (see section V), it is not necessary to respond to this comment.

V. Conclusion

We reviewed the petition and with respect to the petition's first request, we have determined that the dietary exposure to sodium perchlorate monohydrate as a result of the use allowed by the TOR exemption No. 2005–006 does not exceed the TOR exemption criteria in § 170.39(a)(2)(i) and that the data and information provided do not support a conclusion that TOR exemption No. 2005–006 is no longer supportable. With respect to the petition's second request, we decline to propose a regulation under part 189 prohibiting the use of perchlorates as a food contact substance in antistatic agents because proposing such a regulation would be inconsistent with our conclusion that the data and information provided in the petition do not support a conclusion that TOR exemption No. 2005–006 is no longer supportable. With respect to the petition's third request, which is the sole request that is the proper subject of a food additive petition, the food additive use of potassium perchlorate has been removed from § 177.1210 in a final rule published elsewhere in this issue of the **Federal Register** and we decline to address the petitioners' assertions regarding the safety of the food additive use. Therefore, we are denying all three requests, and we are denying the petition in full.

VI. Objections

Any person that may be adversely affected by this order may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

As explained in section II.C, only the petition's request to amend § 177.1210 is within the scope of a food additive petition under section 409(b) of the FD&C Act. The remaining two requests are not within the scope of a food additive petition and our denial of these requests is not an order under section 409(c)(1)(B) of the FD&C Act. Therefore, the provision for objections and public hearing under section 409(f) of the FD&C Act does not apply to these two requests.

VII. References

The following references are on display in the Division of Dockets Management (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. ''Threshold of Regulation Exemptions.'' Available at *https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ThresholdRegulationExemptions/default.htm.*
2. National Research Council. 2005. ''Health Implications of Perchlorate Ingestion.'' Washington, DC. National Academies Press. ISBN 0–309–09568–9. Available at *https://www.nap.edu/catalog/11202/health-implications-of-perchlorate-ingestion.*
3. EPA. 2013. ''SAB Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate.'' EPA–SAB–13–004. Available at *https://yosemite.epa.gov/sab%5CSABPRODUCT.NSF/86E44EE7F27EEC1A85257B7B0060F364/$File/EPA-SAB-13-004-unsigned2.pdf.*
4. Greer, M.A., G. Goodman, R.C. Pleus, et al. 2002. ''Health Effect Assessment for Environmental Perchlorate Contamination: The Dose Response for Inhibition of Thyroidal Radioiodide Uptake in Humans.'' *Environmental Health Perspective.* 110:927–937.
5. National Institutes of Health, ''Hypothyroidism (Underactive Thyroid).'' Available at *https://www.niddk.nih.gov/health-information/endocrine-diseases/hypothyroidism.*
6. EPA. ''Perchlorate (ClO_4) and Perchlorate Salts.'' Available at *https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1007.*
7. EPA. ''White Paper: Life Stage Considerations and Interpretation of Recent Epidemiological Evidence to Develop a Maximum Contaminant Level Goal for Perchlorate.'' 2012. Available at *https://yosemite.epa.gov/sab/sabproduct.nsf/d21b76bff879fa0a8525735a00766807/D3BB75D4297CA4698525794300522ACE/$File/Final+Perchlorate+White+Paper+05.29.12.pdf.*
8. Stedman, T.L. 2006. ''Stedman's Medical Dictionary.'' Philadelphia: Lippincott Williams & Wilkins. 28th ed. ISBN 978–0781733908.
9. FDA. ''Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations.'' Available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm081818.htm.*

10. FDA Memorandum from J. Smith, September 15, 2005.
11. FDA Memorandum from R. Costantino to P. Honigfort, March 31, 2017.
12. FDA. ''Draft Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk.'' December 2016. Available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/ucm528215.htm.*
13. FDA. ''Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations.'' Available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocuments RegulatoryInformation/ucm081825.htm.*
14. Lumen A., D.R. Mattie, and J.W. Fisher. ''Evaluation of Perturbations in Serum Thyroid Hormones During Human Pregnancy Due to Dietary Iodide and Perchlorate Exposure Using a Biologically Based Dose-Response Model.'' *Toxicological Sciences.* 133(2):320–41, 2013.
15. FDA Memorandum from G. Patton, P. Honigfort, and J. Aungst to Administrative File, March 31, 2017.
16. Clapp, S., ''FDA Chemist Says Agency's Food Contact Advice is 'Showing Its Age.' '' *Food Chemicals News.* 53(30): 11–12, 2011.

Dated: April 28, 2017.

Anna K. Abram,

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

[FR Doc. 2017–08987 Filed 5–3–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket Number USCG–2016–0897]

RIN 1625–AA01

Anchorage Ground; Atlantic Ocean, Jacksonville, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend its anchorage regulations to establish a new offshore anchorage area approximately 7 nautical miles northeast of the St. Johns River inlet, Florida. Currently, there is not a dedicated deep draft offshore anchorage for commercial ocean-going vessels arriving at the Port of Jacksonville. Establishing an adequate and dedicated offshore anchorage will alleviate hazardous conditions with vessels anchoring in the common approaches to the St. Johns River. This action is necessary to ensure the safety and efficiency of navigation for all vessels transiting in and out of the Port of Jacksonville. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 5, 2017.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0897 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 Lieutenant Allan Storm, Sector Jacksonville, Waterways Management Division, U.S. Coast Guard; telephone 904–714–7616, email *Allan.H.Storm@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

The Coast Guard, with the recommendation from the St. Johns Bar Pilot Association (SJBPA) and Jacksonville Marine Transportation Exchange (JMTX) Harbor Safety Committee, developed the dedicated offshore anchorage area approximately 7 nautical miles northeast of the St. Johns River inlet, Florida proposed in this notice of proposed rulemaking (NPRM).

The purpose of this proposed rulemaking is to improve the navigational safety, traffic management and port security for the Port of Jacksonville.

Currently, there is not a dedicated deep draft offshore anchorage for commercial ocean-going vessels arriving at the port of Jacksonville. Vessels have routinely been recommended to anchor 1½ nautical miles northeast of the ''STJ'' entrance buoy. However, many mariners are hesitant to anchor in this location due to its proximity to the charted danger area, which is related to unexploded ordinances on the sea floor. Without a designated charted anchorage area, many vessels end up drifting or anchoring in the common approaches to the St. Johns River, creating a potential hazardous condition for all vessels transiting in and out of the Port of Jacksonville. These conditions may worsen with the expected growth in the number of vessels, and the likelihood of large vessels calling on Jacksonville in the near future.

In 2013, Coast Guard Sector Jacksonville hosted a meeting to discuss the establishment of a commercial anchorage off the entrance to the St. Johns River. Members from SJBPA, JMTX, Jacksonville Port Authority, Florida Docking Masters, Army Corp of Engineers, NOAA, local tug companies, and the local Shrimp Producers Association all provided input to the proposed anchorage outlined in this notice. Additionally, in April 2016, Coast Guard Sector Jacksonville conducted a focused Waterways Analysis and Management System (WAMS) study for the proposed offshore anchorage area. No additional findings were found and no comments of concern were received from this WAMS study.

The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 471, 1221 through 1236, 2071; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

III. Discussion of Proposed Rule

The Coast Guard proposes to amend its anchorage regulations to establish an offshore anchorage area approximately seven nautical miles northeast of the St. Johns River inlet, Florida. There currently is not a dedicated deep draft offshore anchorage for commercial ocean-going vessels arriving at the port of Jacksonville. This action is necessary to ensure the safety and efficiency of navigation for all vessels transiting in and out of the Port of Jacksonville. The anchorage area's dimensions are approximately three nautical miles by two nautical miles and would encompass approximately six square nautical miles.

The anchorage boundaries are described, using precise coordinates, in the proposed regulatory text at the end of this notice.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders.

A. Regulatory Planning and Review

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) direct agencies to assess the